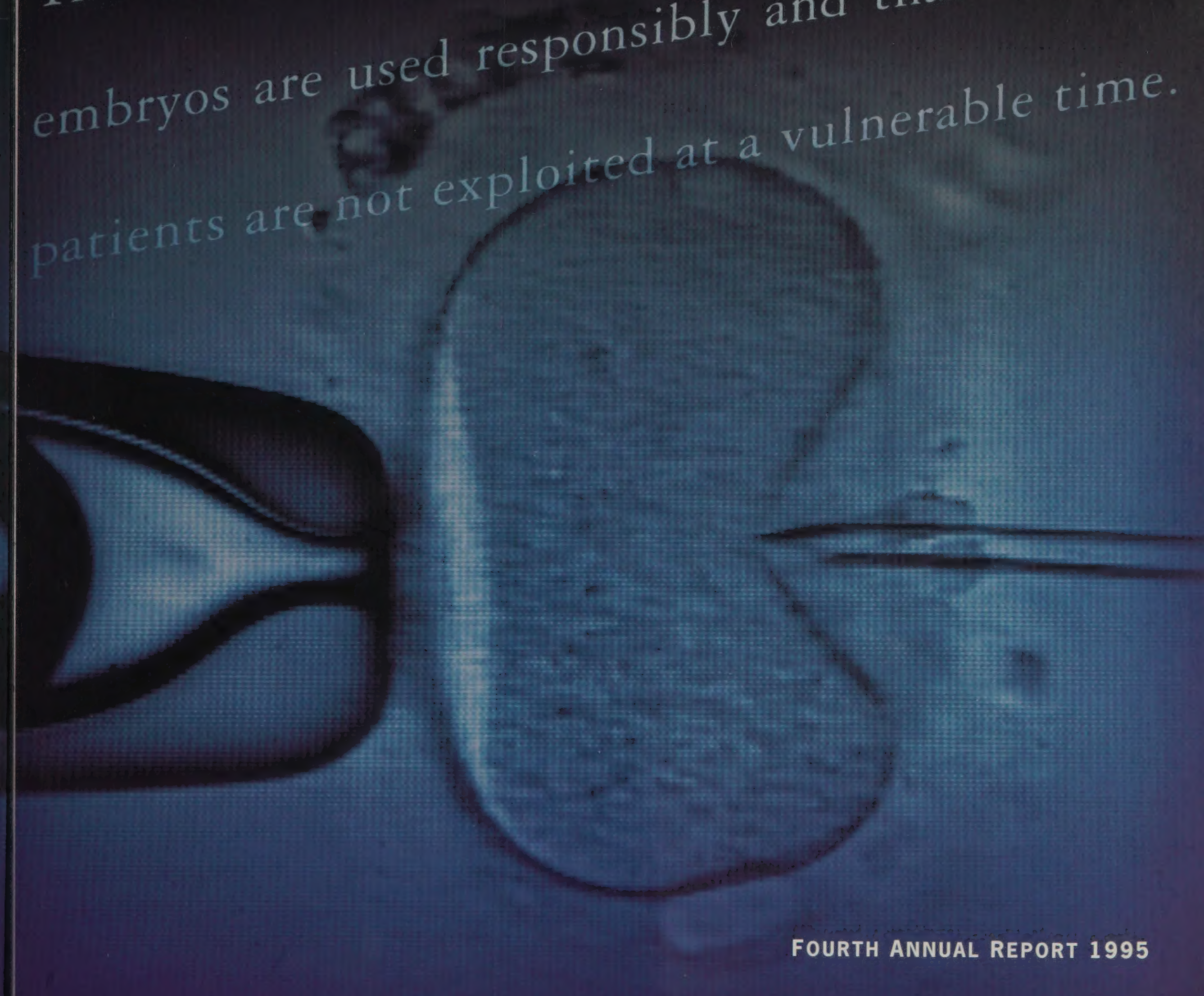
HUMAN
FERTILISATION
&
EMBRYOLOGY
AUTHORITY

As a regulatory body, much of the Authority's work relates to the inspection and licensing of centres carrying out *in vitro* fertilisation (IVF), donor insemination (DI) treatment or embryo research. The members of the Authority ensure that human embryos are used responsibly and that infertile patients are not exploited at a vulnerable time.



FOURTH ANNUAL REPORT 1995

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HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY
PAXTON HOUSE, 30 ARTILLERY LANE, LONDON E1 7LS

THIS REPORT COVERS THE YEAR BEGINNING 1 NOVEMBER 1993
WITH A FORWARD LOOK FOR THE YEAR BEGINNING 1 NOVEMBER 1994

FOURTH ANNUAL REPORT 1995

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THE CHAIRMAN'S FOREWORD

When I was appointed Chairman of the Authority at the end of December 1994, I became aware that it would be no easy task to follow the previous Chairman, Professor Sir Colin Campbell. Sir Colin gave the HFEA leadership and clear direction throughout its first four years. I am grateful to him for the well-run and effective organisation that I inherited.

The HFEA has faced a number of challenges during the past year, challenges it has met with careful consideration and hard work. This report is an overview of its activities during the last 14 months. As the report indicates, it has been a fascinating and instructive time.

Regulation

Given the widespread interest in the HFEA's work over the past four years, members of the public now seem well aware that the principal task of the HFEA is to license and monitor clinics that carry out *in vitro* fertilisation (IVF), the use of donated eggs or sperm (i.e. donor insemination), embryo storage or embryo research. People often ask, however, how this is actually done. In the past, it was primarily through annual inspections.

Last year, the Authority reviewed the effectiveness of its approach to licensing and considered new ways of monitoring the clinics. As a result, it decided to make greater use of information from sources other than inspections (e.g. its treatment database). It will also target the inspections more closely on specific activities in clinics. This should make the licensing process more focused, flexible and efficient. The Authority is also developing ways of monitoring unlicensed clinics involved in transport IVF (see page 9) to ensure that patients receive a proper service throughout their treatment.

Policy and Ethical Issues

The Authority has recently revised its Code of Practice to reflect new developments such as the introduction of Parental Orders. New guidelines on storage of gametes for cancer patients have also been incorporated.

A number of issues have caught wide attention. These have included the Authority's announcement of its decisions following a wide consultation on the use of donated ovarian tissue; and whether regulations should be made to extend the statutory storage period for embryos beyond five years, the current maximum allowed by law.

On the maximum storage period for embryos, the Authority recently submitted a report to the Secretary of State for Health. In the course of preparing the report, the Authority consulted extensively with clinics and patients on the issue. Although the extension of the maximum period is a matter for Government and, ultimately, Parliament, to decide, Authority Members have taken a keen interest in the matter. They will continue to do so with the interests of patients uppermost in their minds.

The Patients' Guide

Each year, the HFEA receives thousands of requests for information. By far, the majority of these concern information on choosing a clinic, and the question most commonly asked is about the results of individual clinics. The Authority has a duty to provide information about the services offered by licensed clinics and believes in principle that it should provide information unless to do it would be harmful or unlawful. The HFEA has sought to find a way of providing comparable information about clinics which is both meaningful to patients and fair to the clinics.

This year will see the first edition of the HFEA's new guide, entitled 'The Patients' Guide to DI and IVF Clinics'. This will become an annual Authority publication. The Guide will offer consistency in the presentation of data within the context of other relevant information about choosing a clinic. The Authority wishes to ensure that patients can obtain the information they need in choosing the clinic they will eventually attend.

Information

Another of the Authority's main duties is to maintain a register of information about all treatment cycles and outcomes of licensed fertility treatment. The register is computerised and contains details of some 100,000 treatment cycles and outcomes. A great deal of work is required to ensure that it is accurate and that it keeps up to date with new ways of providing treatment.

The Authority must always be looking ahead to ensure that the register can fulfil the purpose for which it was set up. This is primarily to meet the needs of the children born as a result of treatment if they wish to find out something about their genetic background or whether they might be related to someone they want to marry. The register is also a valuable tool for the Authority in monitoring clinics. In the longer term, it has the potential to provide clinics with information which could be useful in their own internal audits.

Although the HFEA is not a research body with the expertise to carry out follow-up studies itself, it believes that such studies are very important and wishes to encourage and assist them. One approach under consideration is how the register might be used to achieve this. A most important consideration is, of course, that information containing people's personal details is provided by them in strict confidence and may only be disclosed in the circumstances provided by law. Nevertheless, the Authority is determined to do all it can to assist and support researchers who are interested in follow-up studies on children born through assisted reproductive technologies.

Conclusion

New scientific and medical technology is constantly providing new opportunities for helping people to have children. For example, since 1991, when the Authority took up its full powers, techniques have evolved which allow men previously considered infertile to become fathers of children which are genetically theirs. These are amongst the benefits which the responsible pursuit of science and medicine can bring. But with these developments come new ethical dilemmas, such as the implications for donors of the advances made in identifying the genetic causes of disease.

In keeping with its statutory duty, the Authority will watch carefully the progress of all new developments. It will seek to provide appropriate opportunities for public debate and it will continue to strive to find an acceptable balance between the views of patients, scientists, doctors, ethicists, members of the public and others.

Finally, I wish to record my thanks to the Authority Members for the substantial time and deep commitment they give to the work of the Authority and for the support they have given me in meeting the challenges which the Authority faces. I know that they take very seriously the responsibilities Parliament has placed on them and aim to undertake their task with objectivity, balance and sensitivity.

My thanks are also due to the staff of the Authority, headed by the Chief Executive, Flora Goldhill, for their skill and dedication in this complex area.

The Authority looks forward to another year, which will no doubt bring further new technical developments and ethical issues. Interest in this area is unlikely to wane. The Authority will continue to consult and debate about the many fascinating and important questions that will inevitably arise.

Ruth Deech

RUTH DEECH
CHAIRMAN

THE HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

1

The Human Fertilisation and Embryology Authority (HFEA) is an independent body established by an act of Parliament, the Human Fertilisation and Embryology Act 1990 (HFE Act 1990). It is funded by income from licensing and through a Government grant.

The introduction of the HFEA, which took up its full powers on 1 August 1991, broke new ground in the relationship between medicine, law and ethics. For the first time, an area of medicine, assisted reproduction, was to be controlled by an independent statutory body rather than by voluntary or self regulation.

The Role of the HFEA

The principal task of the HFEA is to license and monitor clinics that carry out *in vitro* fertilisation (IVF), donor insemination (DI) or embryo research. It also regulates the storage of gametes (eggs and sperm) and embryos. In doing so, the Authority seeks to ensure that treatment and research using human embryos are undertaken with the utmost respect and responsibility and that the vulnerability of infertile patients is not exploited.

In regulating treatment and research, the HFEA considers all relevant interests, including those concerning patients, children and potential children, licensed clinics and the wider public. It also takes into account issues of safety, efficacy and ethics.

The HFEA has a number of other main functions under the law which include:

a to keep a formal register of information about donors, treatments and children born from those treatments. This is so that offspring born as a result of donated eggs or sperm can find out, if they wish, something about their genetic background;

b to produce a Code of Practice which gives guidelines to clinics about the proper conduct of licensed activities;

c to publicise its role and provide relevant advice and information to patients and donors and to clinics;

d to 'keep under review information about embryos and any subsequent development of embryos and about the provision of treatment services and activities governed by this [HFE] Act, and advise the Secretary of State, if he asks it to do so, about those matters'.[1]

From the outset, the HFEA's aim in implementing the law has been to set proper standards for clinics and produce guidelines which are practicable for them to follow. At the same time, it has endeavoured to protect the interests of patients and children who might be born and to respond to public concern about the social and ethical implications of the new techniques.

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[1] Human Fertilisation and Embryology Act 1990, section 8 (a)

THE STRUCTURE OF THE AUTHORITY

2

The Members

The HFEA comprises a Chairman, Deputy Chairman and 19 Members, appointed by the Secretary of State, who determine the policy of the Authority and licence applications. The Members bring to the Authority a broad range of medical, scientific, social, legal and religious knowledge and experience. The Human Fertilisation and Embryology Act 1990 requires that the Chairman and Deputy Chairman and at least half of the Members are not involved in medical or scientific practice. A full list of the Members is contained in Annex 1, with committee and working group membership in Annex 2.

The Members are involved in official Authority business on average about three times a month. They attend the monthly meetings of the Authority, chair inspections and sit on the Authority's licence committees and other standing committees and working groups.

The Executive and Committee Structure

The HFEA's Executive comprises a Chief Executive, Deputy Chief Executive and 20 other staff who are responsible for implementing the Authority's policy and undertaking its day to day activities. The Executive is divided into five sections each of which reports to particular HFEA committees or working groups. The sections are:

a Policy and Ethics reporting to the Code of Practice Committee, the Ethics Committee and the Working Group on New Developments in Reproductive Technology;
b Resource Management reporting to the Organisation and Finance Committee;
c Communications reporting to the Communications Steering Group;
d Licensing reporting to the Licensing and Fees Committee and licence committees; and
e Data Management reporting to the Information Committee.

The structure of the Executive is under regular review to ensure it best meets the needs of a small organisation and can respond quickly and flexibly to changing situations.

THE POWERS OF THE AUTHORITY

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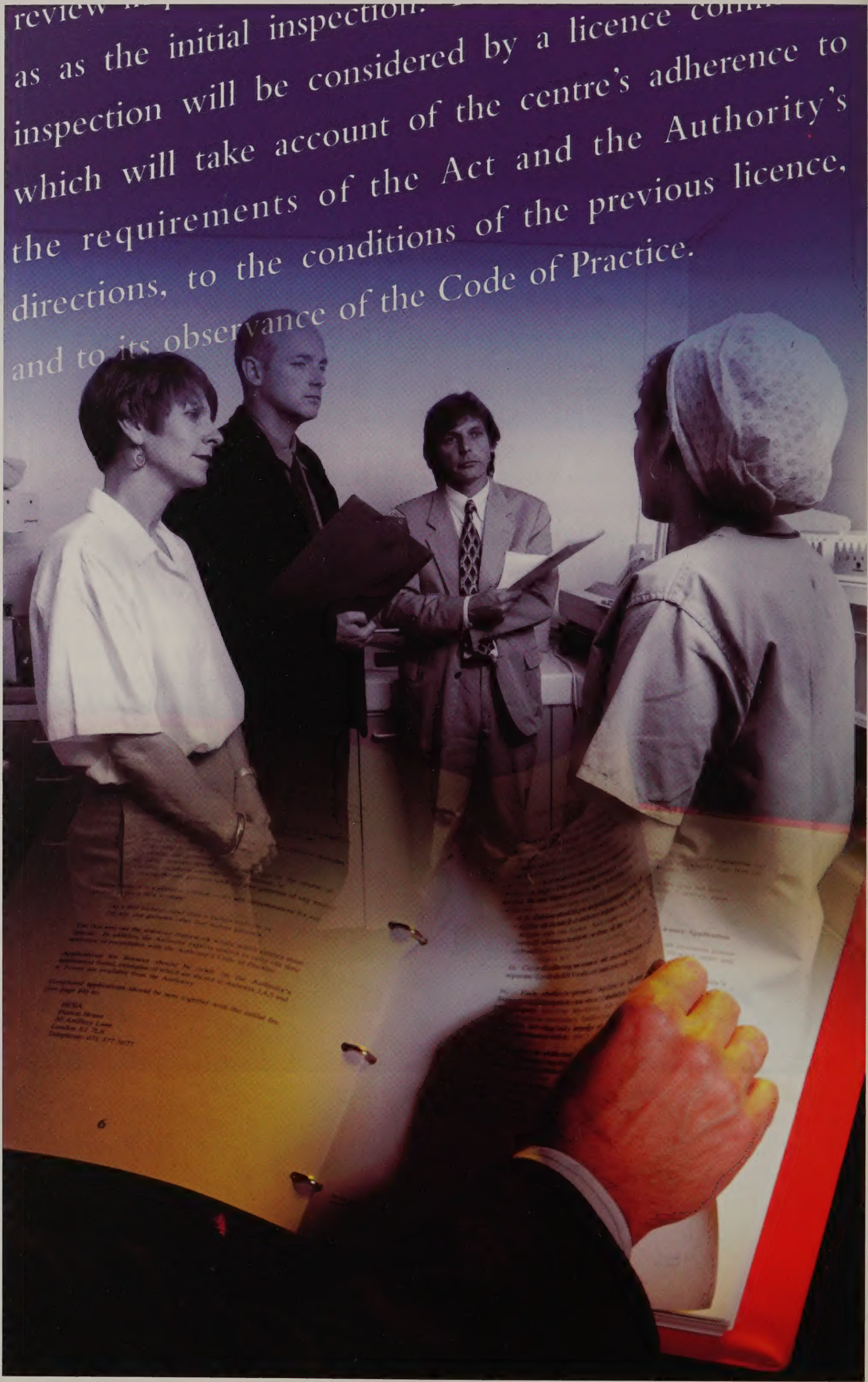

review
as as the initial inspection.
inspection will be considered by a licence
which will take account of the centre's adherence to
the requirements of the Act and the Authority's
directions, to the conditions of the previous licence,
and to its observance of the Code of Practice.
6

Each clinic in the UK which offers IVF or DI, storage of gametes or embryos, or which carries out embryo research is required first to obtain a licence from the HFEA.

The HFEA currently licenses 120 clinics for treatment and/or storage of gametes and embryos. Of these, 69 are licensed for IVF treatment and another 37 for donor insemination only. There are 11 clinics which are licensed only for the storage of sperm. There are 21 research projects undertaken at 17 licensed clinics.

Transport IVF

At the time of publication, there are 16 licensed clinics carrying out transport IVF with 28 satellite clinics. Transport IVF is an arrangement whereby the patient is prepared for treatment and the egg retrieval is carried out in premises which do not require a licence (satellite clinic). The eggs are then transported to a licensed clinic and mixed with sperm to create embryos. The subsequent embryo transfer also takes place at the licensed clinic.

Although involved in the provision of IVF treatment, satellite clinics do not need a licence because they do not carry out any licensable activities. However, the creation or use of embryos can only be carried out by a licensed clinic. Therefore, it is through the licensed clinic that the HFEA ensures compliance with the Human Fertilisation and Embryology Act 1990, Directions and the Code of Practice at all stages in the treatment, including those undertaken at the satellite clinic. If the satellite clinic does not comply with the requirements of the law and the Authority, this could affect the licence of the clinic with which it has the transport IVF arrangement.

The HFEA recognises that transport IVF offers benefits to patients seeking IVF in terms of flexibility in cost and the need for travel. However, it is also aware that there is a risk that the services provided by satellite clinics may not reach the required standards. As a result, it has recently embarked on a rolling programme of visits to satellite clinics and a detailed survey of their practices. Once the survey has been completed, the Authority will review the acceptability of transport IVF.

The Licensing Review

From its inception, the licensing system for clinics was based round the inspection visit and report. The inspection has usually been carried out by a team of four, one of whom would be an employee of the Authority and three others with relevant experience in the provision of patient care. Normally, the chairman of the inspection team would be a Member of the Authority. The inspection team then submits a report to a licence committee made up of HFEA Members. The licence committee decides whether or not to grant a licence and whether any specific conditions should be included. Three years on, the Authority decided it was time to review the effectiveness of this approach and to consider new ways of monitoring the clinics.

The outcome of this review is that the Authority will make greater use of information from other sources in addition to inspections, for instance the HFEA register. It will also use the inspection visit to look in depth at particular activities. More unannounced visits and visits arranged at short notice will be made. Broadly based general inspections of each clinic will continue to be made from time to time.

As these changes are implemented, the licensing process should become more focused, flexible and efficient.

Breaches of the HFE Act, Directions or Code of Practice

In the case of an alleged or apparent breach of the Human Fertilisation and Embryology Act or the Authority's Directions or Code of Practice (see section 4 of this Report), the HFEA makes preliminary enquiries to establish whether there is *prima facie* evidence of a breach. If this is found to be the case, the HFEA will take specialist advice, including legal advice, where necessary.

Information will then be referred to a licence committee which will decide what further action, if any, needs to be taken. Where there is the possibility that a criminal offence may have been committed, a decision will be taken as to whether the matter should be referred to the Director of Public Prosecutions. The question of whether the police should also be involved in any investigation is a matter which is currently under review.

The HFEA insists on the maintenance of proper standards and a breach of the Human Fertilisation and Embryology Act or Directions or the Code of Practice could result in a licence being revoked or suspended. Since it was established, the HFEA has revoked one licence and refused to renew two others. The Authority has also refused to grant several applications for new licences or to vary existing ones.

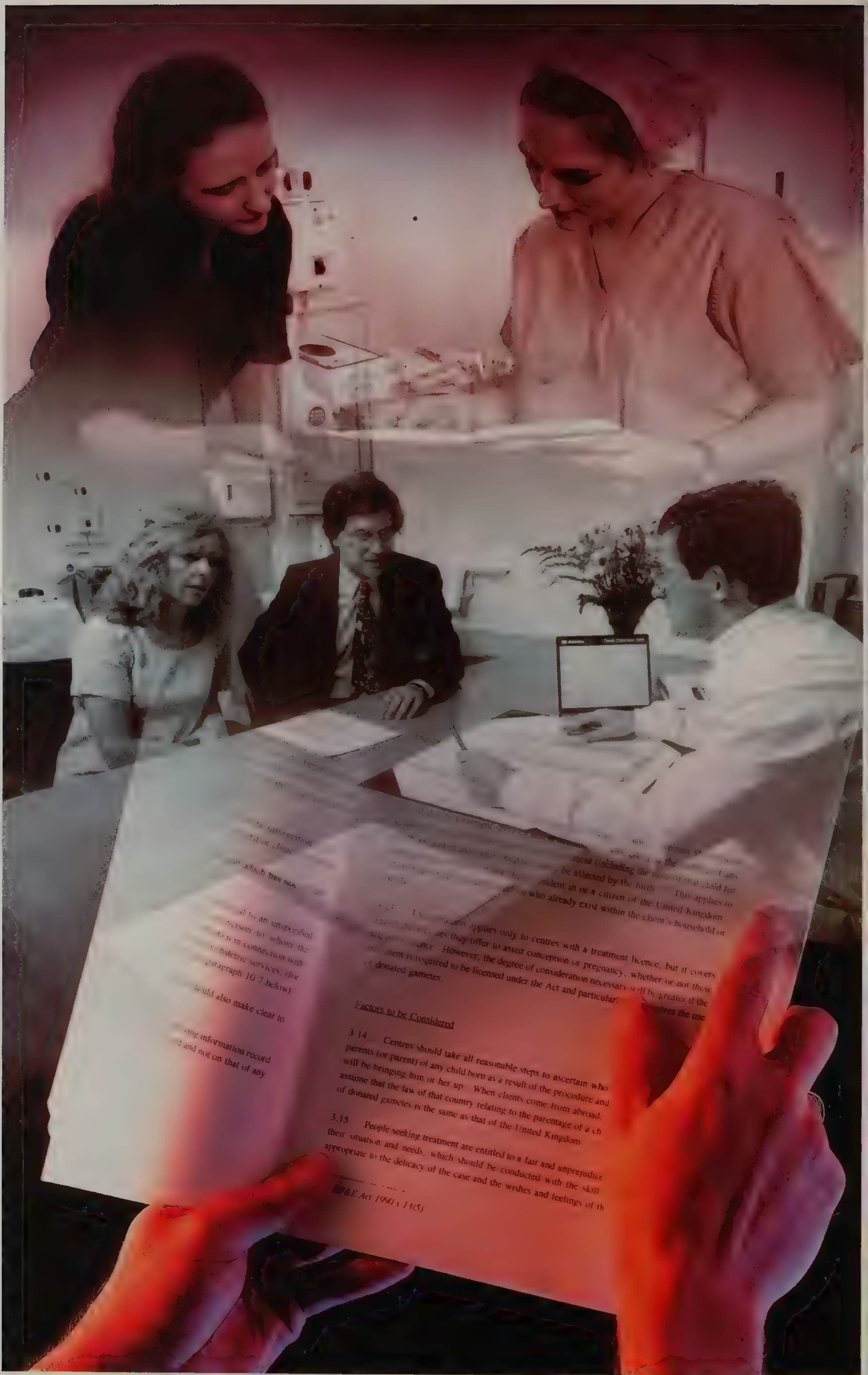
Where an appeal is made by a clinic it is heard by an appeal committee of the HFEA, excluding the Members of the licence committee which made the decision under appeal. An appeal takes the form of a re-hearing and both the appellant and the licence committee are entitled to be represented. If the HFEA decides, following the appeal, to refuse a licence, to refuse to vary a licence or to vary or revoke a licence, there is the right of appeal to the High Court on a point of law.

The Manual for Clinics

The HFEA's 'Manual for Clinics' is issued to all licensed clinics and to new clinics applying for licences. It was revised in August 1994. The Manual contains guidance on the completion of a licence application; details of the licensing process; the representations and appeals procedures; the licence fees structure; the Code of Practice; the information clinics are required to send to the Authority; Directions issued by the Authority; and relevant regulations issued by Parliament.

THE CODE OF PRACTICE

4



Factors to be Considered

3.14 Centres should take all reasonable steps to ascertain who parents (or parent) of any child born as a result of the procedure and will be bringing him or her up. When clients come from abroad, assume that the law of that country relating to the parentage of a ch of donated gametes is the same as that of the United Kingdom

3.15 People seeking treatment are entitled to a fair and unprejudice their situation and needs, which should be conducted with the skill appropriate to the delicacy of the case and the wishes and feelings of th

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&E Act 1990 s 14(5)

The HFEA must by law produce a Code of Practice to guide clinics on how they should carry out licensed activities. All licensed clinics and research clinics are expected to follow the professional, legal and ethical standards set out in the Code and it provides the basis for the Authority's monitoring work.

The Code is regularly reviewed and updated in the light of advances in techniques, and to deal with issues which emerge from the licensing process. The first revision was published in June 1993 and a second revision will appear later this year. Revisions of the Code must be approved by the Secretary of State and laid before Parliament. Copies of the Code are available free on request from the HFEA.

The second revision of the Code of Practice incorporates policy decisions which the Authority has made and notified to licensed clinics since the last edition. These include policy on sex selection of children by means of assisted conception (only permitted in licensed clinics for medical reasons), and policy on cloning by making identical twins artificially (not permitted).

The new edition also explains the requirements of the law on Access to Health Records, and the Parental Orders Regulations 1994. Parental Orders provide a procedure for transferring legal responsibility for a child from birth parents to commissioning parents in surrogacy cases, where one or both of the commissioning parents is genetically related to the child.

The second revision of the Code also contains clarification or further advice on a number of policy issues. These include:

- taking account of the welfare of the child before offering treatment;

- the consent required for use and storage of gametes and embryos;

- responsibility for controlling the number of offspring from a donor; and,
- the relevance of the guidelines in cases where material is stored for cancer patients.

The Code of Practice is kept under constant review and will be revised again when the need arises.

5

The HFE Act, which permits human embryo research only under strict control, states that a developing embryo cannot be kept beyond 14 days after fertilisation or after the appearance of the 'primitive streak', whichever occurs first. The primitive streak occurs when the cells of the embryo separate into those which are to form the fetus and those which will form the supporting structures, such as the placenta and umbilical cord.

Any research on human embryos must be licensed by the HFEA and a licence may only be granted if the proposed research is necessary for at least one of the following purposes:

- to promote advances in the treatment of infertility;
- to increase knowledge about the causes of congenital disease;
- to increase knowledge about the causes of miscarriages;
- to develop more effective techniques of contraception; or
- to develop methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation.

Parliament has decided that certain types of activity involving human embryos shall not be permitted. It is therefore a criminal offence to:

- place a human embryo in an animal;
- place an animal embryo in a woman;
- replace the nucleus of a cell of an embryo with a nucleus taken from another embryo or from a cell of any person; or
- alter the genetic structure of any cell while it forms part of an embryo.

Applications for Research Licences

The Authority has recently reviewed its procedures for granting research licences. It is endeavouring to make the procedure more efficient and effective for all those concerned.

Follow-up Studies

There is no evidence from the studies carried out to date that the incidence of birth defects among children born from licensed treatment is higher than from children born of natural conception. However, the Authority recognises that it would be reassuring to the public and clinicians alike to have information about the development of children born from licensed treatment.

The Authority encourages and supports longer term follow-up studies of the families concerned so that information can be obtained about the physical and psycho-social development of the children.

The Authority is not a research body with the expertise to carry out follow-up studies itself. However, it has considered how it might encourage and assist in follow-up studies and has liaised with a number of professionals and academics working in the field to consider how this might best be achieved. These discussions have taken place within a framework which takes account of legal, ethical and practical considerations. One of the most important is that it is a criminal offence for the Authority to disclose information provided to it about any patient's identity.

However with a patient's consent, information may be disclosed.

The Authority is prepared to consider requests for anonymised statistical information from its database. Such requests would be considered in terms of their potential value, their cost to the Authority and whether the request was considered ethical and practical.

The second way in which the Authority may be able to facilitate research is by helping to identify particular groups of patients who might be asked if they would be willing to take part in a follow-up study. The benefit of this would be that clinics would be saved considerable time and resources identifying and recruiting cohort groups.

The third way in which the Authority is willing to assist is by encouraging, supporting and endorsing appropriate prospective follow-up studies. The Authority will consider a proposal to keep a secure register of patients willing to take part in follow-up studies .

The Working Group on New Developments in Reproductive Technology

During the past year increasing numbers of clinics have wished to offer Intra Cytoplasmic Sperm Injection (ICSI) treatment to their patients.

ICSI can be helpful if the male partner is infertile, i.e. he produces very few sperm. Briefly, ICSI involves producing an embryo *in vitro* by injecting a single sperm, using a very fine glass needle, into the cytoplasm of an egg. The technique is relatively successful in producing embryos. It can be carried out using sperm obtained by testicular biopsy or aspiration.

As a result of the growing interest in ICSI, in 1995, the HFEA set up the Working Group on New Developments in Reproductive Technology. The Group's role includes advising the Authority on the progress and safety of, and the training standards for, new clinical and scientific techniques.

In its first few months, the Working Group discussed the difficulty of managing progression from training to clinical treatment in connection with ICSI and advised the Authority on how this might be achieved under the licensing system.

As a result the Authority is adding additional standard conditions to the licences of those clinics carrying out ICSI in clinical practice. The conditions will enable the Authority to monitor the safety and efficacy of the procedure at individual clinics. There are also conditions to ensure the training and competence of those carrying out ICSI.

SOCIAL AND ETHICAL ISSUES

6

The HFEA regularly consults the medical and scientific professions and the national patient support groups on social and ethical issues. It has consulted the wider public on issues of major importance, such as sex selection and the use of donated ovarian tissue in treatment and in research.

The purpose of consultation, by public debate if appropriate, is to ensure that the issues are fully explored and that the interests of all those involved are properly understood and taken into account before the HFEA reaches any conclusions and gives guidance to clinics, and sometimes to Parliament.

Donated Ovarian Tissue

Last year the HFEA held a consultation on the issues surrounding the use of donated ovarian tissue in embryo research and infertility treatment. The Authority's aim in carrying out the consultation was to inform, to stimulate debate on the issues and to obtain views from the wider public before it became necessary to consider licensing the use of tissue from these sources. The consultation aroused great interest in the media, Parliament and the public. In response to requests 25,000 copies of the consultation document 'Donated Ovarian Tissue in Embryo Research and Assisted Conception' were distributed to organisations and individuals. The Authority received 9,000 responses to the document.

In analysing the responses, the Authority took account of all the views and representations it received. The consultation was not however simply about numbers of responses. Its purpose was to gather arguments and views on the use of three potential sources of ovarian tissue: live donors, cadavers and fetal tissue.

The Authority concluded that in infertility treatment it would be acceptable to use tissue only from live donors. While the Authority had no objection in principle to the use of cadaveric ovarian tissue from adult women, it decided not to approve its use at the present time. The Authority did not consider the use of fetal ovarian tissue to be acceptable in the treatment of infertile women. In the case of embryo research, the Authority agreed that the use of ovarian tissue from live donors, cadavers and fetuses would be acceptable, subject to existing controls.

The number and quality of responses received was remarkable. Many groups and individuals had clearly taken great trouble to produce detailed and thoughtful replies. Responses had been received from individuals and a very wide range of groups, including sixth-form classes, religious groups, village meetings, women's groups, professional scientific, medical and nursing organisations. The experience once again affirmed that this kind of consultation exercise is extremely valuable.

As reported in last year's Annual Report, an amendment to the Criminal Justice and Public Order Bill was put forward which would ban the use of fetal eggs, or embryos derived from fetal eggs, in fertility treatment. The Bill has now passed into law.

The Patients' Guide to DI and IVF Clinics

Each year the HFEA receives thousands of requests for information. The majority of these concern information on choosing a clinic and many people ask for the results of individual clinics.

Most clinics already give out their own results, albeit in raw formats which are difficult to compare. The HFEA's register of information holds comprehensive and validated data for over 40,000 IVF and 60,000 donor insemination treatment cycles. The Authority is therefore in a unique position to publish a guide for patients containing information about the results of treatment at individual clinics.

The HFEA reported last year that it would give further consideration to the best way of presenting comparative statistical information about DI and IVF treatment at different clinics.

The Authority held its fifth public consultation exercise this year when it issued a discussion document explaining its intention to publish treatment results for individual clinics. The exercise began on 19 January 1995 with the publication of the document entitled 'The Publication of Centres' Success Rates for *In Vitro* Fertilisation and Donor Insemination'. Two thousand five hundred discussion documents were sent to licensed clinics, patient groups, health authorities and other interested groups and individuals. The consultation period formally ended on 31 March 1995, following which the Authority arranged meetings in Bristol, Birmingham, Dundee, Manchester and London (2) to discuss the issues with practitioners.

The response to the consultation showed a majority of respondents strongly approving the idea that individual clinics' treatment results should be presented within a guide for patients, which would also contain a wide range of information about choosing a clinic.

Many helpful comments were received regarding the content of the guide and these were incorporated into the final publication.

This will be an annual publication. It will offer consistency in the presentation of treatment and outcome data within the context of a range of other relevant information.

The Payment of Egg and Sperm Donors

Section 12(e) of the HFE Act states that 'no money or other benefit shall be given or received in respect of any supply of gametes or embryos unless authorised by directions'.

In July 1991, the HFEA issued a direction which allows donors to be paid up to £15 per donation plus reasonable expenses. Although this has most commonly applied to sperm donors, the direction also allows women to be offered benefits in the form of treatment services or free sterilisation in exchange for donating eggs.

The direction regularised the position that existed when the HFEA was first set up and the Authority made it clear that the matter would be reviewed within a few years. A Working Group of Authority Members was therefore established in April 1994 to consider the practical, social and ethical issues relating to the payment of sperm and egg donors.

In November 1994, the Working Group reported its findings to the Authority and it was agreed that a conference be held to explore these issues in further detail.

The Conference on the Payment of Donors June 1995

The HFEA conference on payment of donors took place on 1 June at St Anne's College, Oxford, and was chaired by the Authority's Chairman, Mrs Deech. About 80 delegates attended: lawyers, scientists, fertility practitioners, sociologists and experts in bioethics.

The debate was led by two speakers, Reverend Dr David Cook who reviewed the ethical arguments about payment and Professor Ian Cooke who spoke from the experience of his clinic in recruiting sperm donors. In the afternoon, the delegates divided into four groups to discuss particular issues. A wide variety of views was heard and the issues and implications of donation were thoroughly explored.

A consensus emerged among delegates that policy on payment should strive for equity and justice between all parties. There was no wish to see supplies of donated gametes diminish, but on the other hand no wish to see potential donors subject to pressure or excessive inducement. Some delegates suggested that donors should be compensated for inconvenience and that a tariff or notional levels of compensation might be helpful to prevent competition for donors. Interest was expressed in further research into how unpaid donors might be recruited, and there was widespread support for a coordinated effort to raise public awareness of the value and need for egg and semen donation.

A significant point to emerge from the discussions was that the public perception of donation is an important influence on the supply of donors. For the supply of donors to be maintained people need to continue to come forward to donate. Public attitudes evolve over time and this process can be helped by raising awareness of the need for and value of donation. The Authority has been pleased to hear since the conference that the Royal College of Nursing intends to try to set up a body composed of relevant organisations to raise public awareness about donation. The Authority will give this initiative what support it can. It also intends to pursue ideas for pilot schemes to recruit unpaid donors and to carry out further research into the way donors are recruited in other countries. The Authority hopes that public debate on the issue of payment for donors will go forward and will itself continue to consider possible ways forward in more detail.

The GIFT Survey

GIFT (Gamete Intrafallopian Transfer) is not a regulated fertility treatment but there is a regulation-making power in the Human Fertilisation and Embryology Act which could be invoked to make it a licensable activity. The HFEA has undertaken a survey to discover the extent to which GIFT is being carried out in unlicensed clinics.

The HFEA sent a questionnaire to all 1,254 Fellows and Members of the Royal College of Obstetricians and Gynaecologists (RCOG) who were listed as NHS consultant obstetricians and gynaecologists in the UK. In addition, a letter was sent to the Chairman of the RCOG's Scientific Advisory Committee asking whether the Committee was aware of any problems with the provision of GIFT.

Four hundred and eighty-eight questionnaires were returned. Fifty-two came from clinics which performed GIFT, 15 of which were not licensed by the Authority. Four of these 15 were however also involved in transport IVF arrangements with licensed clinics. All but two of the unlicensed clinics involved in GIFT treatment, or planning to introduce it, were based in the NHS.

The survey showed that most GIFT was carried out in HFEA licensed clinics where there is no evidence of inappropriate use. The results of the survey have been passed to the Department of Health.

The Statutory Storage Period for Embryos

The Human Fertilisation and Embryology Act determined that the maximum storage period for embryos should be five years. This took effect from 1 August 1991 and, for all embryos in storage at that date, the five year period ends on 31 July 1996.

The HFE Act does however contain a regulation making power to increase the maximum storage period in specified circumstances and it is for Parliament to decide whether such a regulation should be made.

Since 1991, the law has required that patients must be informed about the maximum storage period, and offered counselling about the implications of this, before consenting to the storage and use of embryos. In giving their consent, the couple must state what should be done with the embryos in the event of their death or mental incapacity. They can contact the clinic at any time to discuss the question of the embryos in storage and vary the terms of their consent.

There are a number of options open to patients within the set time limit for embryo storage. They can consent to the use of the embryos in their own treatment, or for the treatment of others, or for use in research purposes. They can also ask that the embryos be allowed to perish.

The HFEA has looked at all aspects of the storage of embryos to produce a report for the Department of Health. This report addresses the ethical, social, legal and practical arguments for changing the maximum storage period. It is then for the Secretary of State and, ultimately, Parliament to decide whether regulations should be made.

The Authority will be in close contact with its licensed clinics concerning what steps should be taken to ensure that patients are kept abreast of when their embryos will have to be removed from storage.

Training in Infertility Counselling

Section 13(6) of the HFE Act states that people seeking treatment must be given a suitable opportunity to receive proper counselling . During the course of the HFEA's inspections of licensed clinics it became clear that the term 'counselling' could be subject to differing interpretations by the professional groups involved in its provision. This is because there is no coordinated approach to the training of counsellors and no body setting standards. The HFEA therefore facilitated the setting up of the Working Group on Training for Infertility Counselling. This was an independent group, though it was served by HFEA staff and chaired by a Member of the Authority. The Group's remit was to initiate a coordinated approach to infertility counselling and, in order to achieve this, it considered the development and improvement of training for those involved in infertility counselling.

The Working Group recommended that an accreditation body be set up to establish appropriate levels of qualifications, competence and experience for those involved in the infertility counselling process. It then sent out a consultation letter to relevant organisations and held a conference to determine the way forward.

The conference confirmed the proposal that a steering group with members from interested organisations should be set up to help establish an accreditation system. The British Infertility Counselling Association and the British Fertility Society have agreed to take this forward.

COMMUNICATIONS

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As well as licensing research and treatment clinics, the HFEA gives information and advice to people seeking fertility treatment, to donors, to people wishing to store their sperm, or embryos, and to the general public.

The HFEA is performing a unique role in an area of genuine interest and concern to a wide number of people. As such, it places great emphasis on effective communications.

Section 8(b) of the HFE Act requires the HFEA to 'publicise the services provided to the public by the Authority or provided in pursuance of licences'. In fulfilling this function, the HFEA offers a comprehensive range of information including annual reports; a series of explanatory leaflets explaining the Role of the HFEA, Sperm and Egg Donors and the Law, *In Vitro* Fertilisation, Egg Donation, Treatment Clinics: Questions to Ask and Donor Insemination (produced by the RCOG); and lists of licensed clinics. Other publications available include the Code of Practice, consultation documents on sex selection, donated ovarian tissue, individual clinics' treatment results and the Code of Practice on Enforcement. Two videos (on *In Vitro* Fertilisation and Donor Insemination) have also been produced and are available for patients attending licensed clinics which are supplied for educational purposes.

The HFEA presides over a range of activities that are of great and on-going public interest. It is an interest that permeates the national, regional and trade press and television and radio in this country and abroad. As a result, the HFEA is constantly asked to provide resource material to journalists and to 'talk through' particular issues. There is also a steady demand for interviews with HFEA Members.

The range and depth of media interest come as no surprise, for the HFEA operates in an arena that encompasses matters of medical and scientific advance; moral, ethical and religious debate; political and Parliamentary concern; and great human and emotional consequence.

The HFEA also places great emphasis on its role in encouraging informed debate. Members of the Authority and its Executive attend and participate in various conferences; give talks to school and college groups; and attend meetings of medical and scientific organisations and religious, ethical and other relevant groups. The HFEA has been invited to act as observers to two EC groups which meet on bioethics and biotechnology.

Communications Steering Group

The HFEA is now in the process of developing a comprehensive communications strategy to ensure that relevant groups and individuals are aware of the functions of the Authority and that they have accurate information about the work of the Authority.

The communications strategy is being undertaken by the Communications Steering Group which was established in December 1994 and consists of seven Authority Members. Its role is to provide guidance in terms of the publication of HFEA documents, the planning of conferences, the way in which the Authority deals with the public, as well as to steer a way forward in establishing a strategy for the Authority. During the next 12 months, the Communications Steering Group will implement a comprehensive programme to affect all aspects of the Authority's communications.

The HFEA Annual Conference

The HFEA holds an annual conference to provide an important platform for expert opinion and informed debate in the field of regulated fertility treatment. The one day conference gives the staff of licensed clinics, the HFEA's Members, Executive officers, HFEA inspectors and other invited delegates a unique opportunity to discuss issues of mutual interest and to exchange views and ideas.

The HFEA's fourth Annual Conference was held in September 1994. It was well attended: over 200 delegates attended. A number of subjects were addressed which centred around three themes: the publication of clinics' treatment outcomes, the genetic origins of children born from licensed fertility treatment and new developments in assisted reproduction. The speakers at the conference came from licensed clinics, from the Authority and from academic institutions. It was very helpful for the Authority to hear the views of a number of concerned individuals.

The Code of Practice on Enforcement

The HFEA's Code of Practice on Enforcement confirms the level of service that licensed clinics and the public can expect from the Authority. In doing so the HFEA follows the premise that the clinics and the public should have easy access to clear guidance about the Authority's regulations and that they should be able to complain without fear if they are unhappy with the way a regulation has been enforced.

In addition there are appointed persons within the Executive who are responsible for dealing with complaints from clinics, patients and from members of the public. The Code of Practice on Enforcement is sent to the clinics and to Parliament and is available free of charge on request.

The HFEA seeks to achieve the goals set in its Code of Practice on Enforcement in a number of ways.

The Publication of Standards

The HFEA publishes a comprehensive Manual for Clinics (see also section 3 of this Report) which explains inspection, licensing and appeals procedures and contains the Code of Practice for clinics (see also section 4 of this Report).

The HFEA expects to deal with applications within three months. The time scale for issuing research licences can not be so closely defined but these applications are nevertheless dealt with promptly.

Information and Openness

The accounts of the HFEA are a matter of public record and the annual statement of accounts must comply with any direction given by the Secretary of State for Health with the approval of the Treasury.

The HFEA also provides information to clinics, patients and the general public as detailed above.

Complaints

The HFEA stresses that clinics and individuals should not feel inhibited from complaining about the Authority. All written complaints will be followed up promptly with a written reply within three weeks of receipt.

Complaints should be addressed to:
The Chief Executive
The Human Fertilisation and Embryology Authority
Paxton House, 30 Artillery Lane
London E1 7LS

Since the Code of Practice on Enforcement was published in April 1994, there have been six complaints from licensed clinics made about the Authority. Three of these have concerned inspections, two were from licensed clinics about correspondence and one was made about the HFEA's list of licensed clinics.

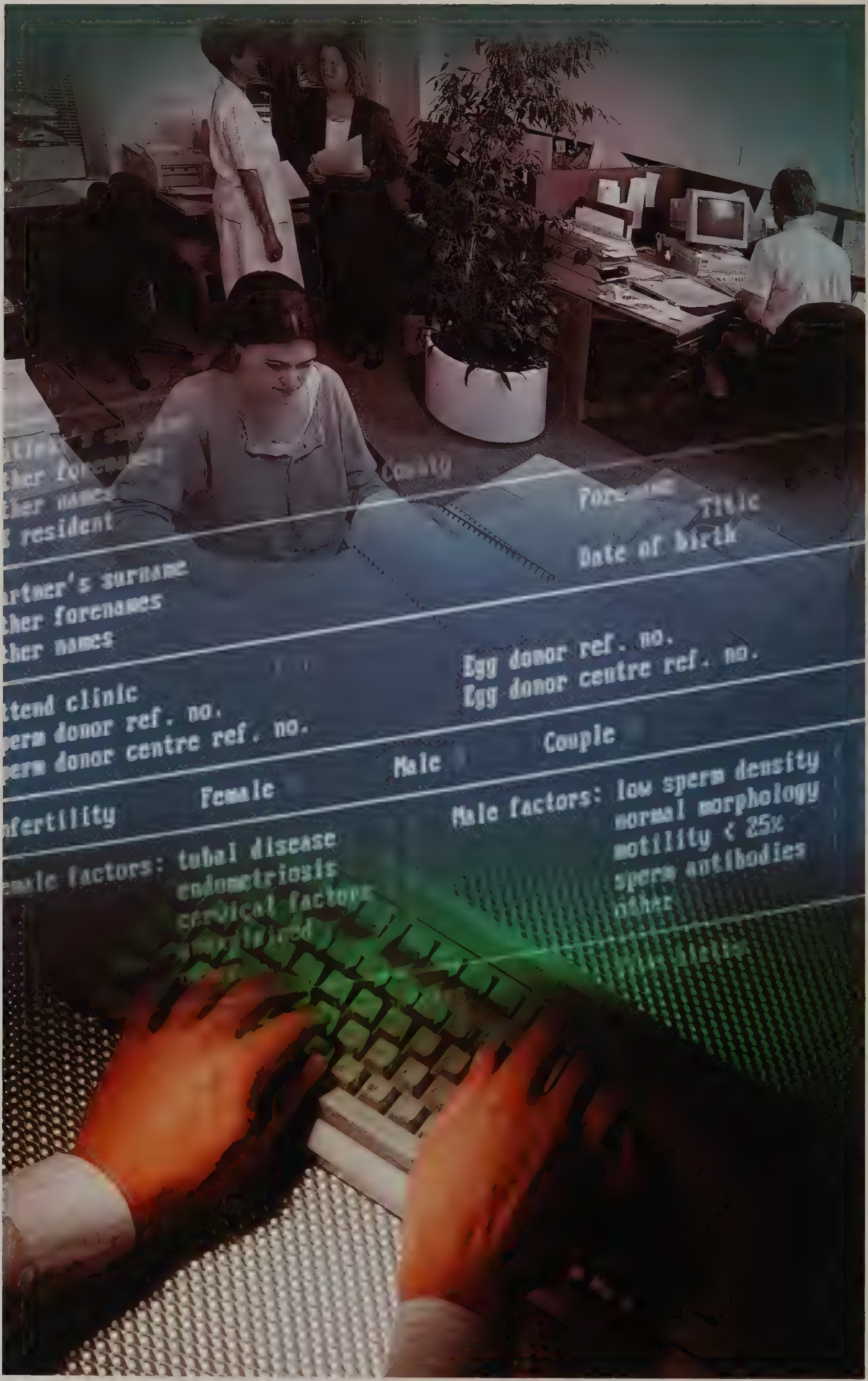
The Authority reviews annually its effectiveness in handling complaints and undertakes to make any changes that are necessary. In addition there is a statutory procedure for appealing against a licence committee's decision (see also section 3 of this Report).

Value for Money

The HFEA seeks to balance the requirements of regulation with the need to minimise the cost imposed on those clinics the Authority licenses and on the taxpayer. The Members and staff of the Authority are constantly aware of the costs of offering and receiving treatment and make every effort to keep administrative costs to a minimum. All expenditure is carefully checked to ensure it is justified and provides good value for money.

THE COLLECTION OF DATA

8



INTRODUCTION

The data presented in this section were compiled from the information collected on the HFEA register and represent the treatments carried out from 1 January to 31 December 1993. During this period there were 65 clinics offering IVF and 95 offering donor insemination. This is the second full year for which the Authority has a complete set of national data. Data from 1985 to 31 July 1991 were provided by the Interim Licensing Authority (ILA).

The Authority is required to collect this information in order that it may give information to children born as a result of licensed treatment. The data also enable the Authority to monitor the provision of IVF and DI and are important for scientists, clinicians and people seeking treatment.

The Authority intends to publish more detailed analysis of particular aspects of the data in an academic journal. In June 1995, it re-established the Information Committee to advise on policy for developing, managing and using this large data set.

In 1993 a total of 18,213 women had 21,823 IVF treatment cycles, including frozen embryo transfers and treatments using donated gametes. There were 8,669 women who had 24,035 DI treatment cycles. For IVF there were 3,921 clinical pregnancies giving a clinical pregnancy rate per treatment cycle of 18.0%, and 3,089 live births giving a live birth rate per treatment cycle of 14.2%. There were 4,177 treatment cycles which were abandoned prior to embryo transfer, 19.1% of all treatment cycles. For DI there were a total of 1,901 clinical pregnancies giving a clinical pregnancy rate per treatment cycle of 7.9%, and 1,517 live births giving a live birth rate per treatment cycle of 6.3%.

The number of pregnancies where no outcomes, or incomplete information, were reported to the Authority totaled 200, or 3.4% of all clinical pregnancies. This is a considerable improvement on the data for 1992 when 404 outcome forms were not received (8.6% of all clinical pregnancies).

IN VITRO FERTILISATION: 1 JANUARY-31 DECEMBER 1993

The IVF data include treatment cycles involving micromanipulation techniques such as ICSI and SUZI. They also include frozen embryo transfers, unless otherwise stated.

IVF Clinical Pregnancy and Live Birth Rates

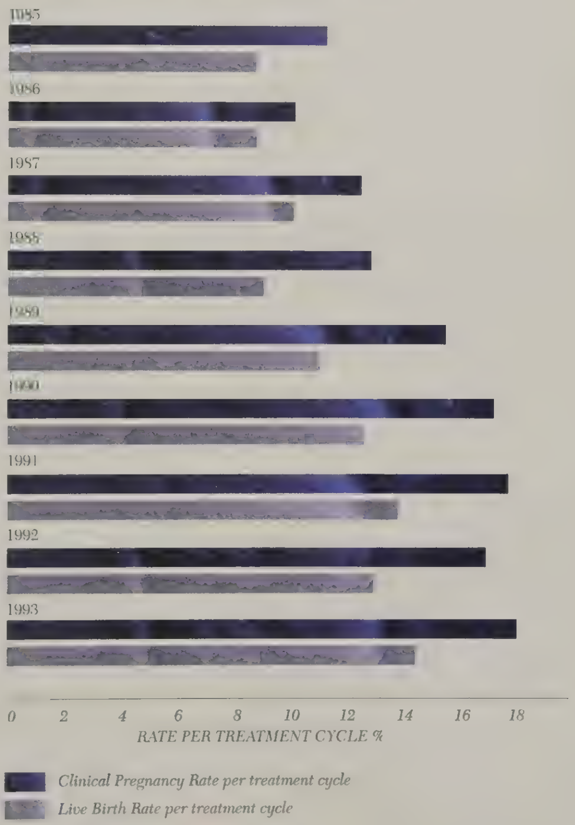
Table 1 shows that both the clinical pregnancy rate and the live birth rate for IVF have increased by over 1% compared with last year. This increase is statistically greater in older women. During this year, the live birth rate has increased for women over 40 from 6.8% in 1992 to 9.3% in 1993.

TABLE 1
IVF CLINICAL PREGNANCY AND LIVE BIRTH RATES: 1985-1993

	CLINICAL PREGNANCY RATE % *per treatment cycle*	*LIVE BIRTH RATE %* *per treatment cycle*	*TREATMENT CYCLES*
1985	11.2	8.6	4308
1986	9.9	8.6	7043
1987	12.5	10.1	8899
1988	12.9	9.1	10489
1989	15.4	11.1	10413
1990	17.3	12.5	11583
1991	17.8	13.9	*6653
1992	16.9	12.7	18224
1993	18.0	14.2	21823

*Data available for 1 August - 31 December 1991 only

CHART 1
IVF CLINICAL PREGNANCY AND LIVE BIRTH RATES 1985-1993



Female Indication for IVF Treatment

Table 2 shows the female indications for treatment. While the majority of treatments with a female factor are due to tubal disease or for unexplained reasons, the clinical pregnancy and live birth rates for all recorded female factors do not differ significantly from each other.

TABLE 2

IVF: FEMALE REASONS FOR TREATMENT

Factors	*Number of Cycles*	*% of all Cycles*	*Live Birth Rate %*
Tubal Disease	9797	44.8	13.2
Endometriosis	2263	10.4	13.2
Unexplained	7883	36.1	14.9
Other	3422	15.6	14.3
All Cycles	23365		14.0

NB: The number of cycles exceeds the total number of cycles for the year (21823) because there may be more than one female factor recorded per patient.

IVF Clinical Pregnancy and Live Birth Rates by Women's Age

Though a greater number of women had IVF treatment in 1993 than in 1992, about the same number of women over 40 had IVF treatment in both years. However, of the women who were over 40 years old at the time of treatment in 1993, a higher proportion had treatment using donor eggs than in 1992.

For women over the age of 25, who have treatment using their own eggs, the pregnancy and live birth rates decrease significantly with age. In treatments using donated eggs, the age of the woman has less of an effect on the pregnancy rate. In older women treated with donor eggs, the slightly higher miscarriage rate may be an indication that deterioration in the quality of the egg is not the only factor in the decreased fertility of older women.

TABLE 3A

IVF CLINICAL PREGNANCY AND LIVE BIRTH RATES BY WOMEN'S AGE (FOR ALL CENTRES, USING OWN EGGS)

	TREATMENT CYCLES	*CLINICAL PREGNANCY RATE % per treatment cycle*	*LIVE BIRTH RATE % per treatment cycle*
Under 25	306	21.2	17.2
25-29	3276	20.9	17.0
30-34	8319	19.7	15.7
35-39	6974	16.7	13.1
40-44	1962	9.5	6.3
45 and over	138	3.1	2.3

CHART 3A

IVF CLINICAL PREGNANCY AND LIVE BIRTH RATES BY WOMEN'S AGE (FOR ALL CENTRES, USING OWN EGGS)

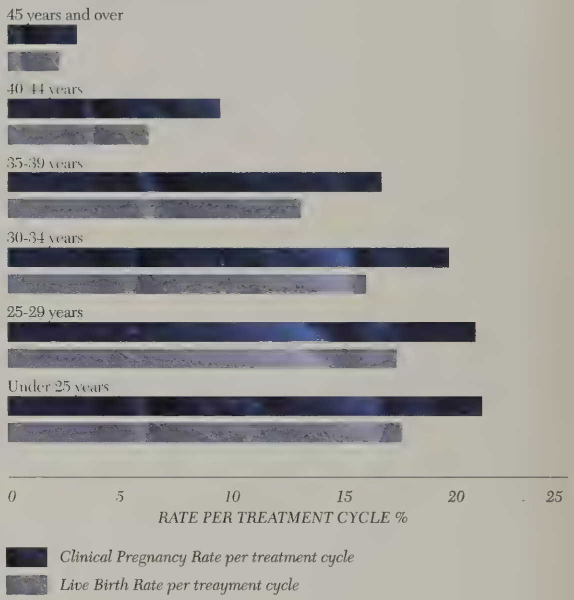
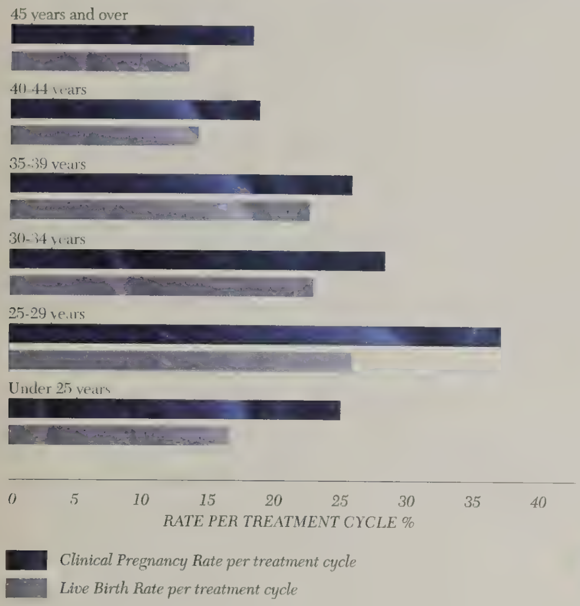


TABLE 3B

IVF CLINICAL PREGNANCY AND LIVE BIRTH RATES BY WOMEN'S AGE (FOR ALL CENTRES, USING DONOR EGGS)

	TREATMENT CYCLES	*CLINICAL PREGNANCY RATE % per treatment cycle*	*LIVE BIRTH RATES % per treatment cycle*
Under 25	16	25.0	16.7
25-29	91	37.1	25.8
30-34	170	28.3	22.9
35-39	196	25.8	22.6
40-44	246	18.8	14.2
45 and over	129	18.3	13.5

CHART 3B
IVF CLINICAL PREGNANCY AND LIVE BIRTH RATES BY WOMEN'S AGE (FOR ALL CENTRES, USING DONOR EGGS)



Single and Multiple Clinical Pregnancy Outcomes from IVF and Frozen Embryo Transfer

The multiple clinical pregnancy rate for IVF fell in 1993 for the third year in succession. In 1991 the multiple clinical pregnancy rate was 29.1%, in 1992 it was 28.2% and for 1993 it decreased to 26.2%.

Of the live births resulting from IVF treatment, 70.1% were singleton, 25.6% were twin and 4.4% were triplet or higher order births. The multiple birth rate for 1993 was 29.9% compared with 31.3% for 1992

The miscarriage rate for singleton, twin and triplet clinical pregnancies are comparable.

The rates of perinatal death of one or more babies were also much higher for a multiple birth. For singletons the proportion of pregnancies that resulted in a perinatal death was 1.0%, for twins 3.8% and for triplets and higher order births it was 4.7%. (In these tables, perinatal deaths are counted separately from live births.)

Multiple Pregnancy Rate by Number of Embryos Transferred

Table 5a indicates that the number of embryos transferred was most commonly three. Three embryos were transferred in 57.2% of all treatment cycles, two embryos in 30.8% and one embryo in 11.9%.

It is widely assumed that replacing three embryos gives the greatest chance of a pregnancy, particularly in older women. Detailed statistical analysis of the data however suggests that once the number of embryos and age are taken

TABLE 5A
IVF MULTIPLE CLINICAL PREGNANCY AND EMBRYO TRANSFER (FOR ALL CENTRES, INCLUDING FROZEN EMBRYO TRANSFERS)

		Number of fetal sacs		
Embryos Transfered	*Number of Transfers*	*Singleton*	*Twin*	*Triplet or Greater*
One	2104	179	3	0
Two	5435	892	239	5
Three	10088	1736	605	144
Totals	17627	2807	847	149

TABLE 5B
IVF CLINICAL PREGNANCY AND MULTIPLE CLINICAL PREGNANCY RATES PER EMBRYO TRANSFER (FOR ALL CENTRES, INCLUDING FROZEN EMBRYO TRANSFERS)

Embryos Transfered	*Clinical Pregnancy Rate %*	*Multiple Clinical Pregnancy Rate %*
One	8.7	1.6
Two	20.9	21.5
Three	24.6	31.2

TABLE 4
SINGLE AND MULTIPLE CLINICAL PREGNANCY OUTCOMES AFTER IVF OR FROZEN EMBRYO TRANSFERS (FOR ALL CENTRES)

	Clinical Pregnancies	*Miscarriages*	*Terminations*	*Ectopics*	*Unknown Outcomes*	*Live Births*	*Babies Born*	*Perinatal Deaths*
Singleton	2807	373	22	112	110	2164	2250	27
Twin	847	96	4	7	11	790	1444	32
Triplet	148	18	4	0	3	134	348	7
Quads	1	0	0	0	0	1	4	0
Totals	3803	487	30	119	124	3089	4046	66

•18 Clinical pregnancies recorded with no outcome form recieved
•Twin and triplet pregnancies do not add up to 100% because a multiple pregnancy may have more than one outcome

into account, the live birth rate is similar for a two embryo transfer and a three embryo transfer. This may be because clinicians select younger, more fertile women for the two embryo transfer.

DONOR INSEMINATION: 1 JANUARY-31 DECEMBER 1993

The DI data includes treatment cycles involving intrauterine insemination (IUI) and GIFT using donor gametes.

There are two main types of donor insemination treatment: stimulated, where ovulation is induced by drug treatment, and unstimulated, or natural, donor insemination where the treatment relies on the one egg produced naturally each month.

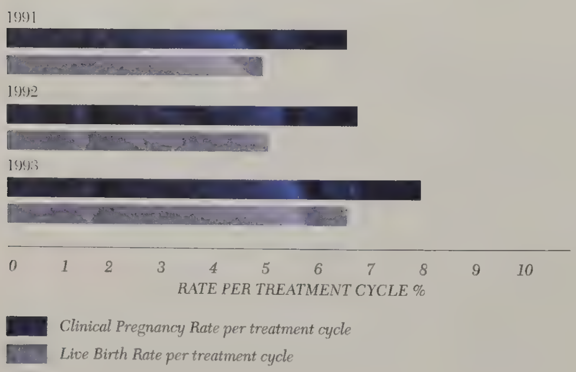
DI Clinical Pregnancy and Live Birth Rates

Table 6 shows that there has been a 7.8% decrease in the number of donor insemination treatments in 1993, with over 2,000 fewer treatments than in 1992. This may be due, in part, to the increase in the use of ICSI to treat infertility caused by a male factor. The clinical pregnancy rate and live birth rate for this year have increased by just over 1% in both cases.

TABLE 6
DI CLINICAL PREGNANCY AND LIVE BIRTH RATES PER TREATMENT CYCLE 1991-1993

	CLINICAL PREGNANCY RATE % per treatment cycle	*LIVE BIRTH RATE % per treatment cycle*	*CYCLES*
1991	6.5	4.9	9262
1992	6.7	5.0	26063
1993	7.9	6.5	24035

CHART 6
DI CLINICAL PREGNANCY AND LIVE BIRTH RATES 1991-1993



DI Data

The table shows that the majority of treatments (59.4%) were unstimulated. This treatment has a lower clinical pregnancy rate (7.5%) and a slightly lower live birth rate (6.0%) than stimulated DI treatment (8.5% and 6.7% respectively).

TABLE 7
DONOR INSEMINATION DATA (FOR ALL CENTRES)

	Unstimulated Cycles	*Stimulated Cycles*
Number of Centres	89	96
Number of Patients	4988	3681
Number of Treatment Cycles	14274	9761
Total Clinical Pregnancies	1071	830
Clinical Pregnancy Rate per Cycle	7.5%	8.5%
Total Miscarriages	127	97
Total Terminations	6	4
Total Ectopics	12	9
Total Live Births	859	658
Live Birth Rate per Cycle	6.0%	6.7%
Total Perinatal Deaths	9	3

Single and Multiple Clinical Pregnancy Outcomes for DI

The overall multiple clinical pregnancy rate including unstimulated and stimulated cycles was lower for DI than it was for IVF. It was 7.8% for DI compared with 26.2% for IVF.

The tables here show that the multiple clinical pregnancy rate for unstimulated DI (2.9%) was much lower than that for stimulated (14.1%). The twin pregnancy rate was 12.2% in stimulated treatment and 2.6% in unstimulated, and the triplet rate was 1.9% compared with 0.3%. The risks of multiple pregnancy is, therefore, reduced in unstimulated DI.

Of the live births reported for stimulated DI, 84.3% were singleton, 13.4% were twin and 2.3% were triplet. For unstimulated DI, 96. 8% of live births were singleton, 2.7% were twin and 0.3% were triplet.

The miscarriage rates for stimulated and unstimulated DI were comparable. The rate of perinatal death in DI treatment was considerably less than for IVF. For stimulated DI the rate was 0.4% and for unstimulated DI it was 0.9%, compared with 1.9% for IVF. This could be because there were significantly fewer triplet pregnancies for DI than for IVF, 18 compared with 148.

TABLE 8A
DI: SINGLE AND MULTIPLE CLINICAL PREGNANCY OUTCOMES FOR STIMULATED DI (FOR ALL CENTRES)

	Clinical Pregnancies	*Miscarriages*	*Terminations*	*Ectopics*	*Unknown Outcomes*	*Live Births*	*Babies Born*	*Perinatal Deaths*
Singleton	677	91	4	8	17	555	557	2
Twin	96	6	0	1	1	88	177	1
Triplet	15	0	0	0	0	15	45	0
Totals	788	97	4	9	18	658	779	3

* 42 Clinical pregnancies recorded with no outcome form received

TABLE 8B
DI: SINGLE AND MULTIPLE CLINICAL PREGNANCY OUTCOMES FOR UNSTIMULATED DI (FOR ALL CENTRES)

	Clinical Pregnancies	*Miscarriages*	*Terminations*	*Ectopics*	*Unknown Outcomes*	*Live Births*	*Babies Born*	*Perinatal Deaths*
Singleton	1001	125	5	12	19	832	832	9
Twin	27	2	1	0	1	24	45	0
Triplet or greater	3	0	0	0	0	3	9	0
Totals	1031	127	6	12	20	859	886	9

* 40 Clinical pregnancies recorded with no outcome form received

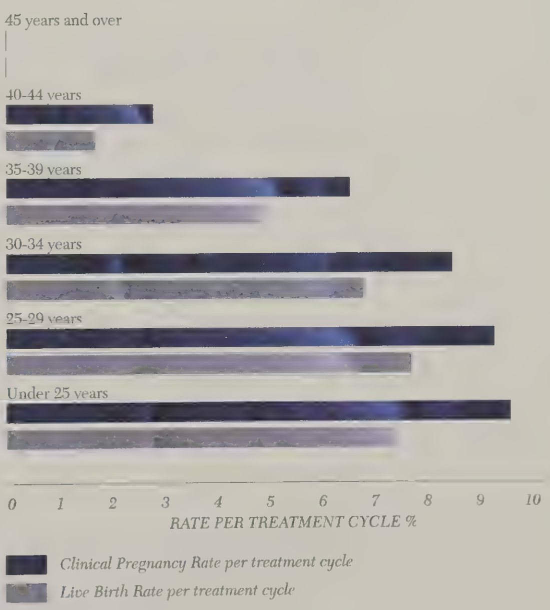
DI Pregnancy and Live Birth Rates by Women's Age

Table 9 shows that the live birth rate from DI decreases with age in the same manner as IVF treatment. There were no clinical pregnancies or live births recorded in women over the age of 45.

TABLE 9
DI CLINICAL PREGNANCY AND LIVE BIRTH RATES BY WOMEN'S AGE (FOR ALL CENTRES)

	TREATMENT CYCLES	CLINICAL PREGNANCY RATE % *per treatment cycle*	LIVE BIRTH RATE % *per treatment cycle*
Under 25	1024	9.6	7.4
25-29	6457	9.3	7.7
30-34	9360	8.5	6.8
35-39	5635	6.4	4.9
40-44	1482	2.8	1.7
45 and over	77	0.0	0.0

CHART 9
DI CLINICAL PREGNANCY AND LIVE BIRTH RATES BY WOMEN'S AGE



A further breakdown of the data to provide more information of special interest is provided in Annex 6.

ISSUES FOR THE COMING YEAR

9

Forthcoming Issues

The Authority will be monitoring developments in the following areas over the coming year.

Preimplantation Diagnosis

In preimplantation diagnosis, cells are removed from embryos *in vitro* and tested to detect their sex or a genetic disorder. This allows a woman at risk of having a child with a life-threatening disorder to have unaffected embryos transferred to her womb, so that she may produce a healthy child.

Last year's Annual Report noted that preimplantation diagnosis was available in clinical practice at one clinic. The Authority anticipated other clinics might wish to gain the expertise needed to offer the procedure. In fact fewer applications to carry out this procedure have been received than expected. Some work is going forward under research licences and the Authority will continue to keep the matter under review.

In the future, as work on the human genome project moves forward, it will become possible to detect the genes for many more disorders, some possibly of a less serious nature, others more serious but developing later in life. Ethical issues may then arise about the extent to which preimplantation diagnosis should be used in identifying genetic problems.

Genetic screening

The knowledge gained from the human genome project may have particular impact on recipients and donors where donated eggs, sperm or embryos are to be used in treatment.

It is already possible to test for cystic fibrosis. As more tests for genetic disorders are developed, there will be implications for patients, potential children and donors and also for their families. Increased testing of donors for carrier status of genetic diseases could lead to a reduction in the availability of donated sperm, eggs and embryos for treatment and, therefore, of treatment itself. People might not be willing to come forward as donors because they do not wish to be screened for genetic disorders. Of those who do come forward, some will discover that they are carriers with all the implications that has for themselves and their families and they too will not be used as donors.

The Authority will be looking at these issues in order to understand how best to reconcile all the interests concerned.

Spermatids in ICSI

In the past, male infertility has been very difficult to treat. However, new developments are taking place which now make it possible for men previously considered infertile to father their own genetic children. One such technique in which there is considerable interest is Intra Cytoplasmic Sperm Injection (ICSI). In ICSI, a single sperm is injected into an egg using a very fine needle. The technique is used with some success to produce embryos *in vitro* when the male partner has very few sperm. Where there are ejaculatory problems, the sperm can be obtained by testicular biopsy or aspiration.

With ICSI, it may be possible to help men who suffer from a disorder which arrests the development of their sperm at a stage when they are called spermatids. A spermatid is larger than a sperm, rounder in shape and has no tail. It does, however, have the necessary number of chromosomes to produce an embryo. Research work is going forward under an HFEA licence to establish the safety and efficacy of using spermatids in treatment with ICSI. (See also section 5 of this Report).

Welfare of the child

The law requires clinics to take account of the welfare of children who may be born, or who already exist, before offering a woman licensed fertility treatment. As part of its monitoring role, during the coming year the Authority will be reviewing the protocols used by clinics in taking account of the welfare of the child.

The HFEA register

The HFEA register of information now contains a large amount of data about patients who have undergone DI or IVF and the outcome of their treatments. This is a valuable resource for research related to treatment. The Authority is willing to consider requests from researchers for access to statistical data subject to the confidentiality requirements of the HFE Act. Development work will take place on the register in the coming year to improve data collection and reporting.

Working Group on the Safe Cryopreservation of Sperm and Embryos

Following a recent report in the *Lancet* (No 8968) entitled “Hepatitis B transmission from contaminated cryopreservation tank”, which involved the storage of bone marrow, the Authority asked a working group of relevant experts to consider whether there are any lessons to be learned for the storage of sperm and embryos. The working group has been asked to draw up, for the Authority’s approval, any necessary advice which can be sent to clinics before the end of 1995.

INCOME AND EXPENDITURE

10

The HFEA Budget

The Authority's budget for the financial year 1994/95 was set at £1.36 million. The Authority is constantly mindful of the need to keep administrative costs to a minimum in order to limit licence fees and the burden on the taxpayer as far as possible. Efficiency savings have been made and the Authority will continue to try to identify new areas where savings can be made without compromising the level of service that it provides.

Licence Fees

In July 1994 agreement was reached with the Department of Health and the Treasury about the amount of the Authority's expenditure to be funded from licence fees. In 1994/95, the level had been set at 60%, rising to 70% in 1995/96. This resulted in an increase in the fees charged to clinics. From 1 September 1994, the fees were set at £40 per IVF cycle and £10 per donor insemination cycle.

From this date the Authority ceased to charge clinics for cycles that were abandoned prior to eggs being mixed with sperm for fresh embryo transfer cycles, and the attempted thawing of embryos for frozen embryo transfers.

HFEA ACCOUNTS 1993/94

Gross Income		
■ Government grant		239,443
■ Income from licensing		757,534
■ Income from other sources		7,300
		1,004,227
Transfer from Reserves		37,959
		1,042,236
Expenditure		
■ Staff costs	488,263	
■ Depreciation	37,959	
■ Other operating charges	619,301	
		1,145,523
Operating Deficit		(103,287)
Income from Investments		868
Deficit for the Financial Year		(102,419)
Appropriations		6,650)
		(109,069)
Retained surplus brought forward		87,927
Retained deficit carried forward		(21,142)

Other operating charges

Accommodation	182,678
Travel & Subsistence - Employees	9,988
Travel & Subsistence - Members	30,385
Travel & Subsistence - Inspectors	54,006
Attendance Fees - Inspectors	30,346
Professional & Administrative Fees	89,763
Audit Fees	12,000
Register of Information	30,490
Stationery & Printing	65,606
Photocopying Charges	5,597
Telephones & Postage	28,039
Communications	10,350
Training & Staff Development	21,584
Recruitment & Advertising	7,546
Conferences & Meeting Expenses	18,878
Library & Reading Materials	7,273
Sundry Office Equipment	20,513
Bad Debts	1,036
Total	619,301

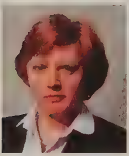
A copy of the Authority's full accounts is available from HMSO.

MEMBERSHIP OF THE HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

CHAIRMAN
Ruth Deech
(from January 1995)
Principal
St Anne's College, Oxford

DEPUTY CHAIRMAN
Diana Brittan
Deputy Chairman, Equal Opportunities Commission;
Magistrate, City of London;
Chairman, Community Industry

Professor Robert Berry
Professor of Genetics,
University College, London



Jane Denton
Nursing Director, Multiple Births Foundation,
Queen Charlottes & Chelsea Hospital, London

Liz Forgan
Managing Director,
BBC Radio

Joan Harbison
Senior Lecturer in Education,
Stranmillis College, Belfast

Professor Stephen Hillier
Professor of Reproductive Endocrinology,
University of Edinburgh

The Most Reverend Richard Holloway
Bishop of Edinburgh

Professor Martin Johnson
Professor of Reproductive Sciences,
University of Cambridge

Richard Jones
Deputy Director of Social Services,
Mid Glamorgan County Council

Penelope Keith
Actress

Dr Brian Lieberman
Medical Director, Regional IVF and DI Unit,
St Mary's Hospital,
Manchester

Angela Mays
Management Consultant

Dr Anne McLaren
Principal Research Associate,
Wellcome CRC Institute

Dr Jeannette Naish
General Practitioner; Senior Lecturer, Department of General Practice & Primary Care, Medical College of St Bartholomew and the London Hospitals, University of London

Rabbi Julia Neuberger
Chairman, Camden & Islington Community Health Services NHS Trust

David Shilson
Bank of England Agent,
Scotland

Professor Allan Templeton
Professor of Obstetrics & Gynaecology,
University of Aberdeen

Julia Tugendhat
Family Therapist,
Westminster Pastoral Foundation

John Williams
Dean, Faculty of Economic and Social Studies,
University of Wales,
Aberystwyth

Professor Sir Colin Campbell
(Chairman until December 1994)
Vice-Chancellor
Nottingham University

Professor Ian Cooke
(until March 1995)
Professor of Obstetrics & Gynaecology,
University of Sheffield,
Jessop Hospital for Women

Professor Antony Cox
(until July 1994)
Professor of Child and Adolescent Psychiatry,
United Medical and Dental Schools of Guy's and St Thomas's Hospitals

Dr Caroline Lindsey
(December 1994-June 1995)
Consultant in Child and Adolescent Psychiatry,
Tavistock Clinic, London

MEMBERSHIP OF HFEA COMMITTEES AND WORKING GROUPS

CODE OF PRACTICE COMMITTEE

Robert Berry (Chairman)
Richard Holloway
Penelope Keith
Anne McLaren
Jeannette Naish
Allan Templeton

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Stephen Hillier
Richard Jones
Brian Lieberman
Angela Mays
David Shilson

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Liz Forgan
Joan Harbison
Julia Neuberger
Julia Tugendhat
John Williams

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Robert Berry
David Shilson
Stephen Hillier

COMMUNICATIONS STEERING GROUP

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Liz Forgan
Joan Harbison
Penelope Keith
Brian Lieberman
Angela Mays
Julia Neuberger

INFORMATION COMMITTEE

Jeannette Naish (Chairman)
Jane Denton
Martin Johnson
Allan Templeton
Julia Tugendhat
John Williams

WORKING GROUP ON DEVELOPMENTS IN REPRODUCTIVE TECHNOLOGY

Anne McLaren (Chairman)
Jane Denton
Stephen Hillier
Martin Johnson
Richard Jones
Brian Lieberman
Allan Templeton

WORKING GROUP ON PAYMENT OF DONORS

Joan Harbison (Chairman)
Jane Denton
Martin Johnson
Brian Lieberman
Angela Mays
Jeannette Naish
David Shilson

AUDIT COMMITTEE

Julia Tugendhat (Chairman)
Richard Jones
John Williams

LIST OF CLINICS CURRENTLY LICENSED BY THE HFEA FOR TREATMENT

AVON
Royal United Hospital, Bath
St Michael's Hospital, Bristol
Southmead General Hospital, Bristol (2)
Tower House Clinic, Bristol
University Of Bristol IVF Service, The BUPA Hospital, Bristol

BERKSHIRE
Berkshire Independent Hospital, Reading
The Orchid Centre, BUPA Dunedin Hospital

BUCKINGHAMSHIRE
BMI Chiltern Hospital, Great Missenden

CAMBRIDGESHIRE
Bourn Hall Clinic, Cambridge
Rosie Maternity Hospital, Cambridge

CLEVELAND
Hartlepool General Hospital
North Tees General Hospital
South Cleveland Hospital, Middlesbrough
Cleveland Fertility Centre, Stokesley

DERBYSHIRE
Derby City General Hospital

DEVON
The Nuffield Hospital, Plymouth
Royal Devon & Exeter Hospital

DORSET
The Winterbourne Hospital, Dorchester

EAST SUSSEX
Esperance Private Hospital, Eastbourne

ESSEX
Holly House Hospital, Buckhurst Hill
The BUPA Roding Hospital, Ilford
North East London Fertility Services, Ilford

GREATER MANCHESTER
Manchester Fertility Services, BUPA Hospital
St Mary's Hospital, Manchester
Withington Hospital, Manchester
Hope Hospital, Salford
Billinge Hospital, Wigan

HAMPSHIRE
Basingstoke District Hospital
BUPA Chalybeate Hospital, Southampton
Princess Anne Hospital, Southampton

HERTFORDSHIRE
Hertfordshire Fertility Services, Queen Elizabeth II Hospital
Watford General Hospital

HUMBERSIDE
The Princess Royal Hospital, Hull

KENT
Chelsfield Park Hospital
Maidstone District General Hospital
Queen Mary's Hospital, Sidcup

LEICESTERSHIRE
BUPA Hospital, Leicester
Leicester Royal Infirmary

LONDON (CENTRAL)
Bridge Fertility Centre, London Bridge Hospital
Dr G B Carruthers, Wimpole Street
The Churchill Clinic
The Cromwell Hospital
Cromwell/St Georges Fertility Centre, St George's Hospital
Dr Louis Hughes, Harley Street
Dr Katz, University College Hospital
The Lister Hospital
London Fertility & Gynaecology Centres (2)
London Wellbeck Hospital
London Womens' Clinic/Hallam Medical Centres (4)
Middlesex Hospital
The Portland Hospital
Pregnancy Advisory Service
St Bartholomew's Hospital
UMDS Guy's and St Thomas's Hospital
University College Hospital (UCH)
West Middlesex Hospital

LONDON (EAST)
The Homerton Hospital
Newham General Hospital
The Rowan Clinic, Royal London Hospital

LONDON (NORTH)
Highgate Private Hospital

LONDON (SOUTH)
King's College Hospital

LONDON (WEST)
Wolfson Family Clinic, Hammersmith Hospital
The IVF Unit, The Royal Masonic Hospital

MERSEYSIDE
Fazakerley Hospital, Liverpool
The Rodney Fertility Clinic, Liverpool
The Women's Hospital, Liverpool
BUPA Murrayfield Hospital, Wirral

NORTHERN IRELAND
Royal Maternity Hospital, Belfast

NORFOLK
BUPA Hospital, Norwich

NORTHAMPTONSHIRE
Three Shires Hospital, Cliftonville

NOTTINGHAMSHIRE
BMI Park Hospital, Arnold
Nottingham City Hospital
NURTURE, University of Nottingham

OXFORDSHIRE
Churchill Hospital, Headington
John Radcliffe Hospital, Headington

SCOTLAND-GRAMPIAN
Aberdeen Maternity Hospital

SCOTLAND-HIGHLAND
Raigmore Hospital, Inverness

SCOTLAND-LOTHIAN
Royal Infirmary of Edinburgh
Western General Hospital, Edinburgh

SCOTLAND-ORKNEY
Balfour Hospital, Orkney

SCOTLAND-STRATHCLYDE
Glasgow Nuffied Hospital
Glasgow Royal Infirmary
Ross Hall BMI Hospital, Glasgow
Monklands District General Hospital, Airdrie

SCOTLAND-TAYSIDE
Ninewells Hospital, Dundee

SHROPSHIRE
Royal Shrewsbury Hospital

STAFFORDSHIRE
North Staffordshire Hospital, Stoke-on-Trent

SURREY
The Woking Nuffield Hospital

TYNE & WEAR
Centre for Reproductive Medicine, RVI Newcastle upon Tyne
Sunderland District General Hospital
Cromwell IVF And Fertility Centre, Washington Hospital

WALES (SOUTH GLAMORGAN)
University Hospital Of Wales, Cardiff
BUPA Hospital Cardiff

WALES (WEST GLAMORGAN)
Singleton Hospital(a), Swansea
Neath General Hospital

WEST MIDLANDS
Midland Fertility Services, Aldridge
Birmingham Maternity Hospital
BMI Priory Hospital, Birmingham
The Walsgrave Hospital, Coventry

YORKSHIRE (SOUTH)
Doncaster Infertility Services
Jessop Hospital For Women, Sheffield
Sheffield Fertility Centre

YORKSHIRE (WEST)
Clarendon Wing, Leeds General Infirmary
St James's University Hospital Trust, Leeds

CLINICS WITH STORAGE LICENCES ONLY
Royal Sussex County Hospital, Brighton
Danum Lodge, Doncaster
St David's Hospital, Gwynedd
Blackdown Nursing Home, Leamington Spa
Bridge Fertility Centre Donor Bank, London
Diagnostic Andrology Services, London
Queen Charlotte's and Chelsea Hospital, London
The Walm Lane Clinic, London
Newcastle General Hospital
Nottingham City Hospital
Singleton Hospital(b), Swansea

LIST OF CURRENT RESEARCH PROJECTS

CENTRE FOR REPRODUCTIVE MEDICINE, NEWCASTLE UPON TYNE
A study of the role of intracellular calcium in the development of human pre-implantation embryos

Human implantation *in vitro*

EDINBURGH ROYAL INFIRMARY
Cell biology of human spermatozoa

GLASGOW ROYAL INFIRMARY
Cytogenetic analysis of aged oocytes fertilised by ICSI

HAMMERSMITH HOSPITAL, LONDON
To measure the activity of metabolic enzymes in spare human pre-implantation embryos

To measure the activity of enzymes implicated in genetic disorders

Pre-implantation genetic diagnosis parallel investigations

KING'S COLLEGE HOSPITAL(a), LONDON
Investigation of the effects of co-culture with the endometrial cells on the viability of human pre-implantation embryos

KING'S COLLEGE HOSPITAL(b), LONDON
Does fertilisation promoting peptide (FPP) stimulate human sperm penetration of zona-free hamster oocytes?

LEEDS GENERAL INFIRMARY
The use of human embryos to develop pre-implantation diagnosis techniques

LONDON WOMEN'S CLINIC/HALLAM MEDICAL CENTRE
Intracytoplasmic single spermatid injection of 1-day old unfertilised human oocytes and the culture of any embryos generated for 6 days post injection to monitor their development

MRC EETU ST GEORGE'S HOSPITAL, LONDON
Cryopreservation of human oocytes

ST BARTHOLOMEW'S HOSPITAL, LONDON
Release of lymphokines by the human embryo

UMDS GUY'S AND ST THOMAS'S HOSPITAL, LONDON
The use of unfertilised human oocytes to assess the fertilising ability of human spermatozoa via ICSI

Improving methods for the biopsy and diagnosis of inherited genetic disease of human pre-implantation embryos

UNIVERSITY OF BRISTOL
Effects of substances and procedures on the ability of human spermatozoa to penetrate zona-free hamster eggs

UNIVERSITY COLLEGE HOSPITAL, LONDON
Pre-implantation diagnosis of genetic disease

UNIVERSITY OF WARWICK
Use of co-cultures in human IVF

UNIVERSITY OF YORK
Biochemistry of early human embryos

WALSGRAVE HOSPITAL, COVENTRY
Use of co-cultures in human IVF

WITHINGTON HOSPITAL, MANCHESTER
In vitro development and implantation of normal human pre-embryos and comparison with uni- or poly-nucleate pre-embryos

LIST OF CURRENT HFEA INSPECTORS

PROFESSOR JOHN AITKEN
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Royal College of Nursing

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MS HILARY EVERETT
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MS MARGARET INGLIS
Counsellor, Royal Free Hospital, London

MS JANICE KERR
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PROFESSOR NORMAN NEVIN
Professor of Medical Genetics, Queens University, Belfast

PROFESSOR JOHN NEWTON
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MRS FELICITY SIEGHART
Justice of the Peace, London

MR ERIC SIMONS
Medical Director, Cromwell Hospital, London

MS JENNIFER SPEIRS
Director, Family Care, Edinburgh

PROFESSOR WILLIAM THOMPSON
Professor of Obstetrics & Gynaecology, Queens University, Belfast; Formerly member of the ILA; Formerly Chairman of the RCOG Fertility Sub-Committee

MRS SHEILA WALKER
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DR PETER WARDLE
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REVEREND PROFESSOR PAUL F WATSON
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DR SARAH WEST
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DR MAUREEN WOOD
Senior Scientific Officer, MRC Experimental Embryology & Teratology Unit, London

DR ROBERT YATES
Medical Research Director of Assisted Conception Unit, Royal Infirmary, Glasgow

DATA TABLES OF SPECIAL INTEREST

TABLE 1A
RESULTS OF STIMULATED IVF AND FRESH EMBRYO TRANSFER CYCLES (ALL CENTRES)

(All percentages are of number of treatment cycles)

	Patients	*Treatment Cycles*	*Cancelled/Failed Egg Collections*	*Embryo Transfers*	*Clinical Pregnancies*	*Miscarry*	*Terminations*	*Ectopics*	*Unknown Outcomes*	*Live Births*	*Babies Born*	*Perinatal Deaths*
Own Gametes	12940	15589	3412 (21.9%)	12176 (78.1%)	2767 (17.7%)	360	17	94	100	2147 (13.8%)	2824	50 (0.3%)
Donated Sperm	1574	1836	181 (9.9%)	1641 (89.4%)	476 (25.9%)	42	7	9	12	400 (21.8%)	569	6 (0.3%)
Donated Eggs	94	100	27 (27.0%)	73 (73.0%)	27 (27.0%)	3	1	1	0	21 (21.0%)	26	1 (1.0%)
Donated Embryos	15	15	1 (6.7%)	14 (93.3%)	5 (33.3%)	1	0	0	0	4 (26.7%)	4	0 (0.0%)
Totals	14623	17540	3621 (20.6%)	13904 (79.3%)	3275 (18.7%)	406	25	104	112	2572 (14.7%)	3423	57(0.3%)

TABLE 1B
RESULTS OF STIMULATED IVF AND FRESH EMBRYO TRANSFER CYCLES (LARGE CENTRES)

(All percentages are of number of treatment cycles)

	Patients	*Treatment Cycles*	*Cancelled/Failed Egg Collections*	*Embryo Transfers*	*Clinical Pregnancies*	*Miscarry*	*Terminations*	*Ectopics*	*Unknown Outcomes*	*Live Births*	*Babies Born*	*Perinatal Deaths*
Own Gametes	10916	13260	2906 (21.9%)	10354 (78.1%)	2441 (18.4%)	307	13	82	93	1907 (14.4%)	2510	46 (0.3%)
Donated Sperm	1301	1518	132 (8.7%)	1378 (90.8%)	411 (27.1%)	36	6	8	12	347 (22.9%)	493	4 (0.3%)
Donated Eggs	78	84	21 (25.0%)	63 (75.0%)	23 (27.4%)	3	1	0	0	18 (21.4%)	22	1 (1.2%)
Donated Embryos	11	11	1 (9.1%)	10 (90.9%)	3 (27.3%)	1	0	0	0	2 (18.2%)	2	0 (0.0%)
Totals	12306	14873	3060 (20.6%)	11805 (79.4%)	2878 (19.4%)	347	20	90	105	2274 (15.2%)	3027	51 (0.3%)

TABLE 1C
RESULTS OF STIMULATED IVF AND FRESH EMBRYO TRANSFER CYCLES (SMALL CENTRES)

(All percentages are of number of treatment cycles)

	Patients	*Treatment Cycles*	*Cancelled/Failed Egg Collections*	*Embryo Transfers*	*Clinical Pregnancies*	*Miscarry*	*Terminations*	*Ectopics*	*Unknown Outcomes*	*Live Births*	*Babies Born*	*Perinatal Deaths*
Own Gametes	2024	2329	506 (21.7%)	1822 (78.2%)	326 (14.0%)	53	4	12	7	240 (10.3%)	314	4 (0.2%)
Donated Sperm	273	318	49 (15.4%)	263 (82.7%)	65 (20.4%)	6	1	1	0	53 (16.7%)	76	2 (0.6%)
Donated Eggs	16	16	6 (37.5%)	10 (62.5%)	4 (25.0%)	0	0	1	0	3 (18.8%)	4	0 (0.0%)
Donated Embryos	4	4	0 (0.0%)	4 (100.0%)	2 (50.0%)	0	0	0	0	2 (50.0%)	2	0 (0.0%)
Totals	2317	2667	561 (21.0%)	2099 (78.7%)	397 (14.9%)	59	5	14	7	298(11.2%)	396	6 (0.2%)

TABLE 2A
RESULTS OF UNSTIMULATED IVF AND FRESH EMBRYO TRANSFER CYCLES (ALL CENTRES)

(All percentages are of number of treatment cycles)

	Patients	*Treatment Cycles*	*Cancelled/Failed Egg Collections*	*Embryo Transfers*	*Clinical Pregnancies*	*Miscarry*	*Terminations*	*Ectopics*	*Unknown Outcomes*	*Live Births*	*Babies Born*	*Perinatal Deaths*
Own Gametes	609	772	455 (58.9%)	317 (41.1%)	43 (5.6%)	5	0	3	0	33 (4.3%)	38	1 (0.1%)
Donated Sperm	51	61	39 (63.9%)	18 (29.5%)	4 (6.6%)	0	0	0	0	4 (6.6%)	7	0 (0.0%)
Donated Eggs	337	371	50 (13.5%)	321 (86.5%)	99 (26.7%)	10	3	0	3	82 (22.1%)	105	1 (0.3%)
Donated Embryos	66	77	12 (15.6%)	65 (84.4%)	24 (31.2%)	6	0	0	1	16 (20.8%)	23	1 (1.3%)
Totals	1063	1281	556 (43.4%)	721 (56.3%)	170 (13.3%)	21	3	3	4	135 (10.5%)	173	3 (0.2%)

TABLE 2B
RESULTS OF UNSTIMULATED IVF AND FRESH EMBRYO TRANSFER CYCLES (LARGE CENTRES)

(All percentages are of number of treatment cycles)

	Patients	*Treatment Cycles*	*Cancelled/Failed Egg Collections*	*Embryo Transfers*	*Clinical Pregnancies*	*Miscarry*	*Terminations*	*Ectopics*	*Unknown Outcomes*	*Live Births*	*Babies Born*	*Perinatal Deaths*
Own Gametes	530	691	408 (59.0%)	283 (41.0%)	37 (5.4%)	4	0	3	0	28 (4.1%)	33	1 (0.1%)
Donated Sperm	37	46	28 (60.9%0	14 (30.4%)	3 (6.5%)	0	0	0	0	3 (6.5%)	6	0 (0.0%)
Donated Eggs	276	304	41 (13.5%)	263 (86.5%)	86 (28.3%)	9	3	0	2	72 (23.7%)	92	1 (0.3%)
Donated Embryos	48	57	12 (21.1%)	45 (78.9%)	20 (35.1%)	5	0	0	0	14 (24.6%)	19	1 (1.8%)
Totals	891	1098	489 (44.5%)	605 (55.1%)	146 (13.3%)	18	3	3	2	117 (10.7%)	150	3 (0.3%)

TABLE 2C
RESULTS OF UNSTIMULATED IVF AND FRESH EMBRYO TRANSFER CYCLES (SMALL CENTRES)

(All percentages are of number of treatment cycles)

	Patients	*Treatment Cycles*	*Cancelled/Failed Egg Collections*	*Embryo Transfers*	*Clinical Pregnancies*	*Miscarry*	*Terminations*	*Ectopics*	*Unknown Outcomes*	*Live Births*	*Babies Born*	*Perinatal Deaths*
Own Gametes	79	81	47 (58.0%)	34 (42.0%)	6 (7.4%)	1	0	0	0	5 (6.2%)	5	0 (0.0%)
Donated Sperm	14	15	11 (73.3%)	4 (26.7%)	1 (6.7%)	0	0	0	0	1 (6.7%)	1	0 (0.0%)
Donated Eggs	61	67	9 (13.4%)	58 (86.6%)	13 (19.4%)	1	0	0	1	10 (14.9%)	13	0 (0.0%)
Donated Embryos	18	20	0 (0.0%)	20 (100.0%)	4 (20.0%)	1	0	0	1	2 (10.0%)	4	0 (0.0%)
Totals	172	183	67 (36.6%)	116 (63.4%)	24 (13.1%)	3	0	0	2	18 (9.8%)	23	0 (0.0%)

DATA TABLES OF SPECIAL INTEREST

TABLE 3A
RESULTS FROZEN EMBRYO TRANSFER CYCLES (ALL CENTRES)

(All percentages are of number of treatment cycles)

	Patients	*Embryo Transfers*	*Clinical Pregnancies*	*Miscarry*	*Terminations*	*Ectopics*	*Unknown Outcomes*	*Live Births*	*Babies Born*	*Perinatal Deaths*
Own Gametes	2034	2421	379 (15.7%)	46	1	10	5	304 (12.6%)	353	5 (0.2%)
Donated Sperm	268	315	52 (16.5%)	8	0	2	1	42 (13.3%)	47	0 (0.0%)
Donated Eggs	169	198	35 (17.7%)	5	0	0	2	27 (13.6%)	38	1 (0.5%)
Donated Embryos	56	68	10 (14.7%)	1	1	0	0	9 (13.2%)	12	0 (0.0%)
Totals	2527	3002	476 (15.9%)	60	2	12	8	382 (12.7%)	450	6 (0.2%)

TABLE 3B
RESULTS FROZEN EMBRYO TRANSFER CYCLES (LARGE CENTRES)

(All percentages are of number of treatment cycles)

	Patients	*Embryo Transfers*	*Clinical Pregnancies*	*Miscarry*	*Terminations*	*Ectopics*	*Unknown Outcomes*	*Live Births*	*Babies Born*	*Perinatal Deaths*
Own Gametes	1731	2058	346 (16.8%)	41	0	10	5	278 (13.5%)	326	5 (0.2%)
Donated Sperm	207	239	43 (18.0%)	5	0	2	1	36 (15.1%)	40	0 (0.0%)
Donated Eggs	156	185	33 (17.8%)	5	0	0	2	25 (13.5%)	35	1 (0.5%)
Donated Embryos	52	64	10 (15.6%)	1	1	0	0	9 (14.1%)	12	0 (0.0%)
Totals	2146	2546	432 (17.0%)	52	1	12	8	348 (13.7%)	413	6 (0.2%)

TABLE 3C
RESULTS FROZEN EMBRYO TRANSFER CYCLES (SMALL CENTRES)

(All percentages are of number of treatment cycles)

	Patients	*Embryo Transfers*	*Clinical Pregnancies*	*Miscarry*	*Terminations*	*Ectopics*	*Unknown Outcomes*	*Live Births*	*Babies Born*	*Perinatal Deaths*
Own Gametes	303	363	33 (9.1%)	5	1	0	0	26 (7.2%)	27	0 (0.0%)
Donated Sperm	61	76	9 (11.8%)	3	0	0	0	6 (7.9%)	7	0 (0.0%)
Donated Eggs	13	13	2 (15.4%)	0	0	0	0	2 (15.4%)	3	0 (0.0%)
Donated Embryos	4	4	0 (0.0%)	0	0	0	0	0 (0.0%)	0	0 (0.0%)
Totals	381	456	44 (9.6%)	8	1	0	0	34 (7.5%)	37	0 (0.0%)

TABLE4
DI CLINICAL PREGNANCY RATES & LIVE BIRTH RATES BY NUMBER OF ATTEMPTS (ALL CENTRES)

	1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*	*14*	*15+*
Patients Treated	3116	2557	2093	1831	1594	1352	1173	1024	891	751	646	559	473	397	2563
Clinical Pregnancy Rates per treatment cycle	9.4	8.8	9.0	7.9	7.3	7.0	7.6	6.6	6.4	6.3	6.3	5.9	6.3	8.3	6.2
Live Birth Rates per treatment cycle	7.4	6.8	6.6	6.3	6.1	5.7	6.6	5.3	4.8	5.1	4.6	4.3	5.1	7.3	4.8

IVF CLINICAL PREGNANCY RATES & LIVE BIRTH RATES BY NUMBER OF ATTEMPTS (ALL CENTRES)

	1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*	*14*	*15*
Patients Treated	5677	2840	1524	825	445	243	152	91	60	51	32	23	16	8	34
Clinical Pregnancy Rates per treatment cycle	19	16.5	17.3	14.3	16.6	12.8	13.8	11.1	8.3	7.8	18.8	4.3	0	2.5	8.8
Live Birth Rates per treatment cycle	14.8	13.5	12.9	11.6	12.8	10.3	11.2	7.7	3.3	7.8	15.6	0	0	2.5	5.9

TABLE 5
NUMBER OF BOYS AND GIRLS BORN FOLLOWING IVF AND DI TREATMENTS

	Boys	*Girls*	*Total*
DI	931 (55.9%)	734 (44.1%)	1665
IVF	2095 (51.8%)	1951 (48.2%)	4046

TABLE 6A
MEAN PREGNANCY AND LIVE BIRTH RATES FOR STIMULATED IVF WITH FRESH EMBRYO TRANSFER CYCLES (ALL CENTRES)

PREGNANCY RATES%

	Number of treatment cycles	*Per Treatment Cycle %*	*Per egg collection %*	*Per Transfer %*
Own Gametes	15589	17.7	20.0	22.7
Donated Sperm	1836	25.9	26.4	29.0
Donated Eggs	100	27.0	–	37.0
Donated Embryos	15	33.3	–	35.7
Total	17540	18.7	20.8	23.6

LIVE BIRTH RATES%

	Per Treatment Cycle %	*Per egg collection %*	*Per Transfer %*
Own Gametes	13.8	15.6	17.6
Donated Sperm	21.8	22.1	24.4
Donated Eggs	21.0	–	28.8
Donated Embryos	26.7	–	28.8
Total	14.7	16.4	18.5

TABLE 6B
MEAN PREGNANCY AND LIVE BIRTH RATES FOR UNSTIMULATED IVF WITH FRESH EMBRYO TRANSFER CYCLES (ALL CENTRES)

PREGNANCY RATES%

	Number of treatment cycles	*Per Treatment Cycle %*	*Per egg collection %*	*Per Transfer %*
Own Gametes	772	5.6	9.6	13.6
Donated Sperm	61	6.6	9.7	22.2
Donated Eggs	371	26.7	–	30.8
Donated Embryos	77	31.2	–	36.9
Total	1281	13.3	18.6	23.6

LIVE BIRTH RATES%

	Per Treatment Cycle %	*Per egg collection %*	*Per Transfer %*
Own Gametes	4.3	7.4	10.4
Donated Sperm	6.6	9.7	22.2
Donated Eggs	22.1	–	25.5
Donated Embryos	20.8	–	24.6
Total	10.5	14.7	18.7

TABLE 6C
MEAN PREGNANCY AND LIVE BIRTH RATES FOR FROZEN EMBRYO TRANSFER CYCLES (ALL CENTRES)

	PREGNANCY RATES%		*LIVE BIRTH RATES%*
	Number of enbryo transfers	*Per treatment cycle %*	*Per treatment cycle %*
Own Gametes	2421	15.7	12.6
Donor Sperm	315	16.5	13.3
Donor Eggs	198	17.7	13.6
Donated Embryos	68	14.7	13.2
Total	3002	15.9	12.7

TABLE 7
DEVELOPMENTAL DEFECTS AND SYNDROMES

CHROMOSOMAL SYNDROMES	*No.*
Down's Syndrome	10
Other chromosomal anomalies	2
CONGENITAL ABNORMALITIES	
Cleft lip with cleft palate	1
Tracheo-oesophagael fistula	2
Cardiac murmurs	1
Ventricular septal defects	2
Other congenital cardiac anomalies	5
Other anomalies of the cardiac septa	3
Anomalies of the umbilical vessels	1
Hypospadias, Epispadias	1
Anomalies of the male external genetalia	5
Renal anomalies	3
Anomalies of urogenital system	1
Polydactyly or syndactyly	4
Talipes	3
Congenital dislocation of the hip	3
Reduction deformities of limbs	2
Other anomalies of the limbs or limb girdle	1
Anomalies of nose, face, skull and neck	3
Musculo anomalies thorax and neck	1
Exomphalos	1
Anomalies of the skin or integument	1
Other unspecified anomalies	2

Some children were born with more than one chromosomal or congenital abnormality.

Out of 5711 children born from IVF and DI treatment, 51 children were born with developmental defects and/or syndromes.

GLOSSARY OF TERMS

Clinical pregnancy Ultrasound evidence of a fetal heart.

Clinical pregnancy rate This is caluclated as a proportion of pregnancies for every 100 treatment cycles.

Cytoplasm The material between the nucleus and the cell surface.

DNA Deoxyribonucleic acid; the part of the cell that contains and transmits the genetic code

Donor insemination (DI) The insemination into a woman of donor sperm (at the cervical opening or into the cervical canal).

Egg retrieval Successful egg collection procedure.

Embryo A fertilised egg between two and eight weeks of development. At two weeks it is approximately 1-1.5 millimetres in diametre.

Embryo transfer Transfer of one or more embryos to the uterus.

Female factor This term covers any reason why a woman is infertile, such as ovulation failure or damage to the fallopian tubes.

Fetus A fertilised egg from eight weeks' development until birth.

Gamete The male sperm or the female egg.

GIFT Gamete Intra-fallopian Transfer. Sperm and a maximum of three eggs are mixed together and transferred to one or both of a woman's fallopian tubes. GIFT is a fertility treatment only licensed by the Authority if donor gametes are used.

Intra Cytoplasmic Sperm Injection (ICSI) A variation of IVF treatment where a single sperm is injected into the inner cellular structure of the egg. This technique is used for couples in which the male partner has severely impaired or few sperm.

In Vitro Fertilisation (IVF) Sperm and eggs are collected and put together to achieve fertilisation outside the body. Up to three of the resulting embryos can be transferred into a woman's uterus.

Intrauterine insemination (IUI) The insemination of specially prepared sperm through the cervical canal into the uterine cavity.

Live birth The delivery of one or more babies.

Live birth rate This is calculated as a proportion of live births for every 100 treatment cycles.

Male factor This term covers any reason why the male partner's sperm may be less effective or incapable of fertilisation, ranging from the absence of viable sperm to a failed reversal of a vasectomy.

Miscarriage Spontaneous complete loss of a pregnancy before 24 weeks.

Miscarriage rate Proportion of pregnancies which miscarry.

Mitochondria Mitochondria are small components in the cell which have their own piece of DNA, distinct from that in the cell nucleus. Eggs are full of mitochondria but sperm have few.

Multiple birth Birth of more than one baby from a pregnancy (these are counted as single live births irrespective of the number of babies).

Multiple birth rate This rate is calculated as a proportion of all births.

Multiple clinical pregnancy Presence of two or more fetal hearts in a pregnancy.

Multiple clinical pregnancy rate This rate is calculated as a proportion of all clinical pregnancies.

Ovulation The release of a mature egg from an ovarian follicle.

Perinatal death The death of a baby either in the uterus after 24 weeks pregnancy (Stillbirth) or within one week after live birth.

Spermatid An immature spermatozoon.

Spermatozoon (pl. spermatozoa) The developed male reproductive cell or gamete.

Stimulated cycle A treatment cycle in which the woman's ovaries are stimulated with superovulatory drugs to produce more than one egg.

SUZI Sub-zonal insemination. A variation of IVF treatment where a single sperm is deposited just beneath the zona (a coat surrounding the egg). This technique is aimed at patients who have sperm which fail to penetrate the zona.

Testicular aspiration Where there is a blockage or an absence to the male duct system, sperm may be collected from the testes.

Testicular biopsy Removal of small section of testes for microscopic examination.

Treatment cycle a) IVF with fresh embryos: a cycle begins with the administration of drugs for the purpose of superovulation, or if no drugs are used, with the attempt to collect eggs.

b) IVF with frozen-thawed embryos: a cycle begins with the removal of the stored embryos in order to be thawed and then transferred.

For DI, a treatment cycle begins when the first insemination with donor sperm takes place.

Unstimulated ('natural') No superovulatory drugs were given to stimulate the cycle.

FRONT COVER PHOTOGRAPH SHOWS INTRA CYTOPLASMIC SPERM INJECTION
TRAINING VIDEO, BRIDGE FERTILITY CENTRE, LONDON

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